EXHIBIT 2

UNITED STATES DISTRICT COURT.
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION — MDL NO. 2875
HON. ROBERT B. KUGLER

THIS DOCUMENT RELATES TO:
In Re: Valsartan, Losartan and Irbesartan Products Liability Litigation,
Case No. 1:19-md-2875-RBK

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HIGHLY CONFIDENTIAL REMOTE VIDEOTAPED DEPOSITION
OF SUSAN BAIN
TUESDAY, JANUARY 31, 2023
6:45 a.m. Pacific Time

Witness' Location:
Walnut, California

TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter as taken by and before DAVID LEVY, a Certified Court Reporter and Notary Public of the State of New Jersey, held remotely over the Internet, on Thursday, January 12, 2023, commencing approximately 6:45 in the forenoon, Pacific Time, pursuant to Notice.

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(All appearances are remote via Zoom conference.)

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^VIDEOGRAPHER: We are going on the record at 6:45 a.m. on January 31st, 2023. This is media unit number 1 of the video recorded deposition of Dr. Susan Bain, regarding the Valsartan litigation. My name is Justin Bily, representing Veritext, and I'm the videographer. The court reporter is David Levy from the same firm. All counsel will be noted on the stenographic record.

Would the court reporter please swear in the witness and then we can begin.

S U S A N B A I N, having been duly sworn by the Notary Public, was examined and testified as follows:

MS. MILLER: Are we ready to begin? Before we begin the deposition, I just wanted to note for the record that I woke up ill today, and I've lost my voice, and I'm going to try to go as long as I can. But I explained to Plaintiff's counsel beforehand that I do not know how long my voice will last today. I apologize for the inconvenience, but these things happen.

EXAMINATION BY
MS. MILLER:

Q. Can you please state your full name for the record.

A. Susan K. Bain.

Q. Where are you today?

A. I'm at my home.

Q. Is anyone there with you?

A. Um -- I have one roommate, not in the same room.

Q. All right. And where is your home?

A. Walnut, California.

Q. You understand that you're under oath today as though you were in a courtroom, correct?

A. Yes, I do.

Q. Have you ever been deposed before?

A. No, I have not.

Q. The main rule is that we shouldn't talk over each other. I'm going to ask questions, you're going to answer them. It's not rocket science. If you need a break, let me know.

Are you in front of a computer right now?

A. Yes, I am.

Q. And do you have any programs up on that computer?

A. No.

Q. Okay. Adam mentioned that you have a lot of documents in front of you. Can you tell me

what those are?

A. Those are -- these are documents that they provided to me, and Adam's people provided to me related to this case.

Q. Okay. And when you say you have them in front of you, are they hard copies or do you have them on the computer?

A. I have several binders and I have all of them on the computer. Electronically.

Q. Okay. If you at any point in this deposition look on your computer at a document, please let me know.

A. Okay.

Q. And who prepared the binders?

A. Adam's people.

Q. All right. And you don't have e-mail or messaging apps up on your computer?

A. No, I do not.

Q. Can you hear me okay despite my weak voice?

A. Yes, I can.

Q. And you're able to give full and complete testimony today?

A. Yes, I am.

Q. How many binders do you have with you

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today, can you show them to me? Is there a way to show them?
A. I can --
Q. You're --
A. -- spread about here, the largest one, deviation investigations. Well, I don't know what -- you can't see it, probably.
Q. No. You've just -- your hand is --
A. I don't know how to get it to you. Do I go out, maybe? I'm not sure how to get you to see it.
Q. That's so strange.
A. It is strange, right?
Q. Yes. So you have --
A. Message --
Q. Now I can see it.
A. Okay, there we go.
Q. How many of those binders do you have about that size?
A. Oh, this is the largest one.
Q. Okay. And have you taken notes in those binders?
A. No.
Q. Are the documents highlighted?
A. No, they are not.

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Q. Okay. Have you read the complaint in this case?
A. I'm sorry?
Q. Have you read the complaint in this case?
A. Yes.
Q. When did you read it?
A. I want to make one correction, please. I have a binder that also has my report.
Q. Okay.
A. And in this binder I do have tabs.
Q. And what are the tabs --
A. I'm sorry?
Q. Tabs but not writing, you said?
A. Correct.
Q. And what do the tabs signify?
A. Different sections within my report, different names of people who've testified. So mostly sections.
Q. Okay. We were talking about the complaint in this matter, and I was asking when you read it.
A. I can't give you an exact date but very early on when I was retained.
Q. Do you know who the Plaintiff is in this matter right now?
A. Yes.
Q. And who is the Plaintiff?
A. ZHP.
Q. Do you know what a Plaintiff is?
A. Yes.
Q. What is a Plaintiff?
A. The party bringing suit against the Defendant.
Q. And who is bringing the suit?
A. The name that I know of is Adam's law firm.
Q. So you don't know who the actual Plaintiff is?
A. I'm just saying, the people, but I mean if you're asking me a law firm name that's working on, I don't know, other than Adam's law firm.
Q. When did you first get contacted to participate as an expert in this litigation?
A. I don't know the exact date. But it was in the late April, early May time frame in 2022.
Q. And who contacted you?
A. Chris Geddis.
Q. Do you know how Chris identified you?
A. No, I do not.

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Q. Had you ever spoken to Chris before?
A. No, I hadn't.
Q. Have you ever worked on litigation before?
A. No, I haven't.
Q. This is the first time you're serving as an expert in litigation?
A. Yes.
MS. MILLER: Let's mark Susan Bain's report as Exhibit 1.
EXH (Susan Bain Exhibit 1, expert report of Susan Bain, DRSc, dated 10/31/22, 109 pages, marked for identification, as of this date.)
Q. If we could turn to page 2 of your report, your background and qualifications.
A. Um-hum.
Q. It says that you spent several years working at the FDA as a Consumer Safety Officer/Investigator.
Do you see that?
A. Can you pointing to me exactly --
MS. MILLER: Alex?
A. Yes.
Q. Do you see it, several --
A. Yes.

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Q. Is that accurate?
A. Definition of "several." I began in early 2002 and ended my time there in, toward the end of 2003.
Q. So you worked there for a year-and-a-half?
A. A little over.
Q. Is that several years?
A. Again, the definition of "several." To me it's close.
Q. Did you write that sentence?
A. Yes.
MR. SLATER: Please don't ask any questions about the writing of the report. That's off limits under the Federal Rules of Civil Procedure.
Q. What's a Consumer Safety Officer/Investigator?
A. I'm sorry, what was the question?
Q. What is a Consumer Safety Officer/Investigator?
A. The Consumer Safety Officer/Investigator is a person who routinely performs audits of firms that are under the U.S. FDA jurisdiction.
Q. Did you do any work involving drugs?

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A. I did no work in the area of drugs. The work I did was in veterinary drugs.
Q. Was most of your focus on veterinary drugs or on devices?
A. Most of my focus was on medical devices.
Q. What percentage of your work in the year-and-a-half you were at the FDA was on medical devices?
A. I guess I would have to ask you, are you talking about number of days that I spent on devices versus vet drugs, or number of actual inspections?
Q. Either one.
A. I would say approximately, and again, it depends on your definition. Most of my time was on the medical device side. So if that's 60 percent, 70 percent? I can't say for sure sitting here. That was, you know, years back. But most of my time was on the medical device side, and less than fifty percent of my time was on the vet drug side.
Q. You said that was several years back. How many years ago was that?
A. I left in 2003.
Q. So you haven't worked at the FDA in two decades, correct?
A. Approximately, yes.

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Q. And to the extent you worked on drugs, you said it was veterinary drugs?
A. Yes, it was.
Q. Did you ever review the Drug Master File?
A. No, I didn't.
Q. Did you ever review an ANDA?
A. No, I did not.
Q. Did you ever conduct an inspection at an API manufacturer?
A. No, I did not.
Q. In your time at the FDA, your brief time at the FDA, did you find your colleagues to be professional and dedicated?
A. Yes, absolutely.
Q. And the FDA is charged with protecting public health by ensuring that pharmaceutical products are safe and effective, correct?
A. Yes.
Q. And why did you leave?
A. I really enjoy working in industry. And I had spent a number of years in the industry prior to going to the FDA. And I truly missed working in industry. So I went back to industry.
Q. And what did your work with respect to

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medical devices entail at the FDA?
A. Doing inspections.
Q. What were you inspecting?
A. Manufacturing sites.
Q. And did you have a supervisor who supervised that, the inspection?
A. Absolutely.
Q. And what was that person's title?
A. Supervisor.
Q. Were you a junior person in the ranks there?
A. Yes, I was.
Q. Have you ever worked for an API manufacturer?
A. I worked for Watson Pharmaceuticals, a generics company.
Q. When was that?
A. When I left the FDA, it was -- I began in 2003, at the end of 2003 -- the end of 2003. I continued there until early 2005.
Q. And what was your job at Watson?
A. I was one year in regulatory affairs. I was the regulatory affairs manager, and then I moved back to quality, which was -- it's my passion. And I was a quality assurance -- I'm sorry, I believe it --

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I don't remember the exact title, honestly. Quality assurance manager. It might have been possibly corporate quality assurance manager. I don't remember for sure.
Q. Were you involved in any inspections by the FDA of Watson, on the Watson side?
A. No, I was not.
Q. Were you involved in any recalls?
A. Yes.
Q. Which recall?
A. At the time, Watson was undergoing a number of recalls on various products.
Q. I'm asking what those products were.
A. Oh, my goodness. I honestly -- I couldn't tell you at this point. I honestly don't remember what exact products were being recalled during that one year.
Q. What was your role with respect -- do you not recall because there were multiple recalls?
A. Yes, that is true. I was in charge of the coordination of the recalls.
Q. Were there warning letters will in conjunction with any of those recalls?
A. Watson was under a consent decree at that time.

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Q. What kind of consent decree?
A. For GMP violations.
Q. Do you recall what the GMP violations were?
A. No, I don't.
Q. And did you have a role in responding to any FDA inquiries regarding the GMP violations?
A. No, I did not.
Q. Do you know if Watson received any 483 letters during your time there?
A. I do not know.
Q. Do you know whether Watson received any warning letters during your time there?
A. I don't know. I wasn't part of that.
Q. Was your job solely to handle the logistics of recalls?
A. Yes.
Q. Do you recall whether any of the products that were being recalled during your tenure at Watson were recalled because they posed a risk to patient safety?
A. I don't recall what the reasons were for the recalls. I was in charge of, actually, as you said, logistics and confirming that product was returned from the field.

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Q. So you don't know sitting here today whether any of those products posed any sort of risk to patient safety or health.
A. I would assume they did because they were recalled.
Q. And do you know whether, typically when there is a product recall, it results in a warning letter?
A. Not necessarily.
Q. Do you know what percentage of recalls result in warning letters?
A. I do not.
Q. Were you responsible for communicating with the FDA about the product recalls?
A. No.
Q. Have you ever had a role in any company in which you were responsible for communicating with the FDA about product recalls?
A. No.
Q. Have you ever had any employment position where you were responsible for responding to a 483? And I assume you know what a 483 is.
A. Yes, I know what a 483 is. Where I was responsible for -- position title, position responsibility, if we had received a 483, yes, we

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would have been responsible for responding to those parts in the 483 that pertained to my department.
However, communication directly with the FDA would go through regulatory affairs.
Q. And which job are you talking about right now?
A. Multiple positions.
Q. Do you recall any company that you worked for receiving a 483?
A. While I was employed with the company?
Q. Yes.
A. Sorry, I have to think for a second.
Q. No problem.
(A pause in the proceedings.)
A. I don't recall working at a company at the time they received the 483.
Q. Do you recall working at any company at the time they received a warning letter?
A. No, I did not work any place that received a warning letter during my tenure.
Q. Do you recall working at any company other than Watson that had a recall during your tenure there?
A. Yes.
Q. Which company is that?

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A. At the time, the name of the company was Technicoone, T-e-c-h-n-i-c-o-o-n-e.
Q. And you worked there 1996 to 1999?
A. Yes.
Q. And what was recalled?
A. We had a product that was in clinical trials and we ended up having to recall it.
Q. What was the product?
A. I -- I don't know what the exact name was. Again, it was under clinical trial, and we -- I can only tell you what we referred to it as.
Q. Okay.
A. Because it never went to market.
Q. So what did you refer to it as?
A. LYM-1. L-Y-M-1.
Q. And why did it have to be recalled?
A. Because of a raw material that was in -- that we had used in the product that was discrepant.
Q. That was what?
A. Discrepant. It was a bad raw material that was in the product.
Q. Was anyone in the clinical trial injured?
A. No.
Q. Have you ever worked for a company that

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received an LAI from the FDA?
A. During my tenure?
Q. At any time that you're aware of.
A. I haven't reviewed the warning letters for companies I've worked at prior to my arriving. So anything I would say would only be an assumption.
Q. Did you hesitate to join Watson in light of the fact that they were under a consent decree?
A. No.
Q. And why not?
A. It was my understanding at the time that they were working with the FDA under their consent decree and remedying their issues.
Q. So you felt comfortable working with a company that had been subject to regulatory issues as long as they were working on fixing whatever the problem was?
A. Yes.
Q. Did Baxter have a recall while you were there?
A. There was a recall going on during my tenure there that I'm aware of.
Q. Do you remember what it had to do with?
A. No. I don't -- I don't recall.
Q. Do you recall whether patients were

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becoming infected with hepatitis C from a Baxter product?
A. No, I don't recall.
Q. Do you remember having any concerns about working for a company that was conducting a recall involving infection of patients with hepatitis C?
A. I'm sorry, can you restate?
Q. Do you recall having any concerns about working for a company that was conducting a recall because patients had been infected with hepatitis C?
A. No, I did not have any concerns.
Q. Would you be concerned about working for a company that has sold a product that led to infecting patients with hepatitis C?
A. Not as long as it wasn't done intentionally.
Q. Do you know whether Baxter received a warning letter in conjunction with a hepatitis C issue?
A. I don't know.
Q. Now that I've refreshed your recollection, do you remember the hepatitis C issue?
A. I've heard about it but I don't know if that recall, if that specific reason for recall went

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on during my tenure.
Q. You were there in July 1994, correct?
A. Yes.
Q. And do you recall what Watson's CGMP violations were?
A. No.
Q. Have you ever taught a course in organic chemistry?
A. No, I have not.
Q. Have you ever taken a course in organic chemistry?
A. During my undergrad -- let me refresh -- I believe I took a course in -- in introductory organic chemistry in...
Q. What year would that have been?
A. Oh, my goodness.
Q. Sorry to age us.
A. Maybe, again, I'm not sure.
Q. That would have been in the 1970s, correct?
A. Yeah, 1975, '76, something in that area.
Q. So fifty years ago.
A. Yes.
Q. And do you recall learning anything about nitrosamines there?

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A. No.
Q. What's Alpha Therapeutic?
A. A biologics manufacturing company.
Q. And what did you do there?
A. I had several positions there. The first position was as a quality engineer. And then I became manager of raw material receipt. And then I was quality manager of operations.
Q. Did you represent Alpha Therapeutic before the FDA with respect to any inspections or warning letters?
A. No, I did not.
Q. Did you have any interaction with the FDA while at Alpha Therapeutic?
A. No, I did not.
Q. Did you have any interaction with FDA at Watson?
A. No, I did not.
Q. Did you have any interaction with the FDA at Baxter?
A. No, I did not.
Q. Do you recall whether Alpha Therapeutic had a recall while you were working for them?
A. Not to my knowledge.
Q. Were you there in 1990?

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A. No -- yes, I was there.
Q. You have no recollection of a recall at Alpha Therapeutic in 1990 --
A. No.
Q. -- I was in the middle of my sentence. It involved antihemophilic factor prophylate SD, and the recipients of the product were experiencing fever, chilled, nausea and vomiting. Does that ring a bell?
A. No.
Q. So you had no involvement with that recall.
A. No, I did not.
Q. Have you had communications with the FDA in any of your positions? I might short-circuit my questions.
A. I'm trying to recollect whether or not I had any involvement. So I did have involvement when I was at Technicoone with an inspection that they performed at our facility.
Q. And what was that interaction you had with the FDA at Technicoone?
A. It would have been related to our quality system.
Q. So what was the nature of your contact

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with the FDA?
A. If they asked to review the customer complaints or any quality metrics that we might be keeping with deviations or nonconformances. And we would pull those records.
Q. Any other interactions with the FDA during your career?
A. I don't recall any others.
Q. And you don't recall that, while you were at Watson, the company received a warning letter about CGMP violations with respect to antibiotics?
A. No, I don't.
Q. Do you recall that one of the issues raised by the FDA with respect to CGMP violations at Watson involved contamination of antibiotics?
A. No, I don't.
Q. Are you surprised to hear that?
A. Rather.
Q. And why are you surprised if you knew that they were under a consent decree?
A. I -- I didn't know what the specific violations were.
Q. You knew that there were CGMP violations but not what the CGMP violations were?
A. That's correct.

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Q. What does it take to get to the stage where you've got a consent decree with the FDA?
A. Generally, my understanding is that it's a stepwise process where inspections take place at the firm. If there's observations during the inspection, they are noted on a 483. The firm is given the opportunity to respond and correct. Then FDA will come out and perform a reinspection.
If the firm continues to have GMP violations, and/or does not correct the violations or observations that they previously cited, it may result in a warning letter. Then FDA continues to perform inspections by at various intervals.
If companies continue to have issues, the warning letter process can escalate to a consent decree.
Q. So a consent decree is a higher step in terms of violations and -- is a consent decree a final agency action?
A. It's my understanding it could go further. There could be other judicial actions. Whether those are worse or if they are encore, I'm not sure.
Q. Is a warning letter considered a final agency action?

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A. Is it -- I'm sorry?
Q. Is a warning letter considered a final agency action?
A. Final agency action? No.
Q. Why not?
A. Because you could escalate beyond that to a consent decree.
Q. So what is the purpose of a warning letter in that case?
A. The purpose of a warning letter in that case?
Q. What is the purpose of a warning letter?
A. To solicit voluntary compliance.
Q. When you were with the FDA, did you work with the FDA in D.C.?
A. No.
Q. Where did you work for the FDA?
A. The office was located in Irvine, California.
Q. So it was like an outpost?
A. At the time, it was called a district office.
Q. Does FDA still have those?
A. My understanding is, there's been some restructuring, renaming, and they don't identify them

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any longer as district offices.
Q. Have you ever been to FDA headquarters?
A. No, I have not.
Q. Is it fair to say that since leaving the FDA in 2003, you've had no communications or interactions with FDA?
A. Could you please clarify what you mean by "interactions with FDA"?
Q. Have you had any interactions with FDA since 2003?
A. Are you speaking about submissions that might go into the FDA, or a product, or are you talking about direct phone calls? I'm not sure.
Q. Let's take it one at a time. Have you had any phone calls with anyone at the FDA since 2003?
A. Yes.
Q. And when was that?
A. Within the last two years.
Q. And who was your phone call with?
A. I don't recall the person's name. Functionally, he was a person who answers questions for small business companies.
Q. How many times did you speak to him?
A. Once.

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Q. How long was that call?
A. Less than ten minutes.
Q. Have you had any other conversations with anyone from the FDA since 2003?
A. Yes.
Q. What were those?
A. I spoke to a reviewer regarding a submission that the company I was working with had put in.
Q. When was that?
A. When? That was within this last year. 2022.
Q. Do you remember that person's name?
A. Sean, S-e-a-n, Miller, M-i-l-l-e-r.
Q. And how long did that call last?
A. I believe we had two calls and each one was less than ten minutes.
Q. Okay. Any other calls with the FDA since 2003?
A. No.
Q. So three calls all total less than 30 minutes; is that fair?
A. I believe that's fair.
Q. And have you had any meetings at the FDA since 2003?

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A. No.
Q. Has anyone from FDA called you since 2003?
A. No.
Q. Has anyone from FDA asked you to speak or present on any topic, ever?
A. No. I would like to clarify. When you said "interact with people from the FDA," I have been -- had a few interactions with people who work at the FDA and have presented talks through an organization I belong to.
Q. So like you were at a conference and you chatted with someone from the FDA?
A. Yeah. I was on the board for the organization and we asked them if they would please examine and do a presentation for us on a specific topic.
Q. And what was the name of that group that you were involved in?
A. Orange County Regulatory Association.
Q. And so did someone come and speak in Orange County from Washington, D.C.?
A. It was via Zoom.
Q. It was via Zoom. When was that?
A. 2021.

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Q. Figured it was post-2020 when you said Zoom.
A. Yes. And I -- and again, I'm going off memory, we may have also had someone speak in 2020, but that would also be via Zoom.
Q. Do you remember who those people were?
A. I don't recollect at this moment, but I'll think of it and it may come to me a little bit later.
Q. Are you aware that while you were at Watson, the active ingredient for Trazodone was accidentally used in the production of antibiotics?
A. Can you repeat the name of that drug, please?
Q. Trazodone.
A. No.
Q. Do you know what Trazodone is?
A. No.
Q. Do you know what Clindamycin is?
A. I don't know for sure what it is.
Q. Are you aware that Watson was accused of improperly cleaning its equipment?
A. No.
Q. Did you review the consent decrees or warning letters before agreeing to go work at Watson?

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A. No, I did not.
Q. Did you review any warning letters or consent decrees while at Watson?
A. No, I did not.
Q. Why did you leave Watson?
A. I was presented with an opportunity to go to a startup company and that was appealing to me at the time.
Q. And was that startup company Spine-Worx?
A. It was.
Q. And what were they starting up?
A. We designed and developed spinal implants.
Q. When you say "we," were you involved in the design and development of spinal implants?
A. Yes, from the quality side.
Q. What was your job?
A. I was head of regulatory and quality.
Q. And what did that involve doing?
A. Setting up their quality systems.
Q. Did they have inspections while you were there from the FDA?
A. I was just thinking about that. We had one inspection, as I recollect.
Q. Do you know how that inspection went?

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A. Yes, it went well. It was -- we did not receive a 483.
Q. Have you ever been fired from a job, or terminated?
A. Very early on in my career.
Q. Which job was that?
A. That was the position at Calmar, C-a-l-m-a-r.
Q. What year was that?
A. It was approximately 1985.
Q. What did they do?
A. At the time, they did injection molded plastics for closure containers.
Q. And why were you terminated?
A. Let me think back.
(A pause in the proceedings.)
A. I do not remember the reason.
Q. You were fired from one job in your life and you don't remember the reason why?
MR. SLATER: One second, Dr. Bain. Objection, it's argumentative. Let's be respectful and reasonable in how we question a witness. Thank you.
Q. You can answer.
A. I do not remember. I don't remember.

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Q. And did you include that job on your resume?
A. No. I don't believe it's on there.
Q. Why?
A. My resume covers my professional work since I moved into the pharmaceutical industry.
Q. When did you move into the pharmaceutical industry?
A. In 1988.
Q. Did you have any jobs between the Calmar job from which you were terminated and the Alpha Therapeutic Corporation job?
A. Yes.
Q. What did you do in between?
A. I worked at a company that manufactured helicopter blades.
Q. And why did you leave that job?
A. I decided I'd like to work in the pharmaceutical industry because I had a degree in biology and I was interested in the field.
Q. And your first job in the pharmaceutical industry was at Alpha Therapeutical Corporation?
A. Yes.
Q. Was that a manufacturer?
A. Yes.

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Q. What did they manufacture?
A. Rigid plasmapheresis, so plasma-related drugs.
Q. And what was your job there?
A. That's where I had three different positions. I started as a quality engineer, went to a manager of quality receiving raw materials, and then I was promoted to quality manager of operations.
Q. And you don't recall any of the recalls that occurred while you were there?
A. No.
Q. You wouldn't have been involved in recalls while you were at --
A. Not in my position, no.
Q. So the quality position in a pharma company, a person in the quality position isn't involved if a product is recalled for lack of quality?
A. It depends what your job description and function is within the quality unit. So I was --
Q. So other colleagues of yours would have been involved in a recall?
A. I -- I'm not sure. But I would assume -- I'm not sure. I was, honestly, I was focused on my job and what I was doing.

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Q. And do you remember any FDA inspections while you were at Alpha Therapeutic Corporation?
A. I don't remember if FDA came to audit us. I do know we were audited by the French regulatory authorities. But that's the only audit I recall at this time.
Q. Just to be clear, you don't recall any on-site FDA inspections when you were at Alpha Therapeutic.
A. No.
Q. When you were at Technicoone, were you responsible for reporting adverse events to the FDA?
A. No.
Q. When you were at Watson, did you have FDA contact?
A. No, I did not.
Q. When you were at Spine-Worx, did you interface with the FDA?
A. Only during the inspection.
Q. And it was only one time?
A. Yes.
Q. Okay.
MS. MILLER: We've been going about an hour, I need to take a water break. So let's go off the record.

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VIDEOGRAPHER: The time is 7:38. This ends media unit 1. We're going off the record.
(Recess taken.)
VIDEOGRAPHER: The time is 7:52. This begins media unit number 2. We're back on the record.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. Do you recall what month it was when you started at FDA?
A. I believe it was March.
Q. And do you recall what month it was when you ended at FDA?
A. It was either very late November or early December. I don't recall for sure.
Q. Are you at U.S.C. today?
A. Yes, I am. Oh, you mean physically or working?
Q. Physically.
A. Physically I'm at home.
Q. And have you told your employers at U.S.C. that you are testifying today in litigation?
A. I told my department chair I had a deposition.
Q. And did you ask your department chair

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whether it would be okay to use the U.S.C. backdrop for your Zoom for litigation?
A. No, I did not.
Q. Are you here on behalf of U.S.C.?
A. I am not.
Q. Did you ask U.S.C. for permission to serve as an expert in litigation?
A. No, I did not.
Q. Do you know whether U.S.C. allows professors who serve as experts in litigation to use U.S.C. as the backdrop for ear Zooms?
A. I don't know. This is a backdrop from my teaching --
Q. Understood.
A. -- lectures online. So...
Q. Understood. Do you mostly teach online?
A. No, mostly on site.
Q. Do you have tenure at U.S.C.?
A. I'm not in a tenure track position.
Q. Were you in a tenure track position at Claremont?
A. No.
Q. What does it mean to be in a non-tenure track position?
A. It means that you're -- in my case, I'm

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a full-time employee as, in my position, an assistant professor, but not in a tenure track. Our department doesn't have tenure tracks.
Q. And why is that?
A. I don't know. I don't know why.
Q. And what is your salary at U.S.C.?
A. Approximately 150,000, I think. I'm not honestly sure.
Q. And that's considered a full-time job?
A. Yes.
Q. And do you go to the campus every day?
A. No.
Q. How many times a week do you go to the campus?
A. That depends.
Q. On average.
A. I always go a minimum of two days a week during the week. And our particular program in our department is a program that was designed for working professionals, so our classes are held on the weekend.
Q. So let me understand that. You go in on the weekends to teach live?
A. I do.
Q. Saturday and Sunday?

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A. Yes.
Q. And --
A. Not every weekend.
Q. And Monday through Friday you don't go to U.S.C.?
A. I go in two days a week.
Q. So you go in two days a week between Monday and Friday plus Saturdays and Sundays?
A. Some Saturdays and Sundays -- or Sundays.
Q. And you also have a company called InCompliance?
A. I do.
Q. And how many hours a week do you work in that company?
A. That depends. It's a consulting company of myself. So it very much depends on, you know, what -- what, you know, clients and how many clients I might have.
On average -- own average, it's hard to say. On average ten hours a week.
Q. And U.S.C. knows about it?
A. Yes.
Q. Do you need to get permission for outside work?

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A. Yes.
Q. Do you need to get permission for litigation consulting?
A. Not to my knowledge. It's not really a permission, per se. It's more just a notification that I do consulting for the pharmaceutical industry.
Q. Did you ask for approval or seek approval to testify in litigation?
A. I did not. I only made my chair, the chair of our department, aware.
Q. And is the chair of your department tenured?
A. No, not a tenured position, to my knowledge.
Q. And who are your clients at InCompliance?
A. Who are they? I mean, what are you asking?
Q. Can you tell me, can you list your clients?
MR. SLATER: One question, or one point. If there's a confidentiality to any extent of the work you did, and you're not allowed to disclose something for a confidentiality provision, you cannot violate that position.

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THE WITNESS: Okay, thank you.
A. Are you talking about clients I have right this minute, or what specifically?
Q. To the best of your recollection, can you list all the clients you had in that job?
A. Oh, my goodness. I can't -- I cannot list, you know, every client that I've had. And some of my consulting work is with a consulting company.
Q. What do you mean by that?
A. They are a company who hires consultants to perform work for them.
Q. What's that company called?
A. Pharmatech Associates, P-h-a-r-m-a-t-e-c-h Associates.
Q. So you're saying you do work for Pharmatech?
A. Yes.
Q. And Pharmatech hooks you up with companies?
A. Pharmatech actually gets the contract with the firm, and then, depending on what kind of work the firm needs done, they contact a consultant to go out and do that work.
Q. You don't have Pharmatech on your resume.

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A. No, because it's -- they are a client of mine.
Q. Okay. So through Pharmatech, what companies have you worked with?
A. Through Pharmatech -- oh, my gosh -- I've worked with a company called Tissue-Teks. I've spent quite a bit of time with that. I did some work with -- I did an audit of a facility in San Diego called AccuLab. That was -- that was recent. I'm trying to -- I'm trying to remember the names. I don't know, if it's really important, I can -- I can look up some of the names when we're on a break and tell you the names.
Q. We can go back to this after a break, but the two companies you're remembering right now are Tissue-Tek and AccuLab?
A. Yes.
Q. What does Tissue-Tek do? I assume they don't make tissues.
A. No, they are a company who does tissue processing.
Q. What percentage of your work at InCompliance comes through Pharmatech?
A. That very much depends, because, you know, obviously during the pandemic, there were a lot

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of companies who, either they didn't -- didn't do audits or have outside audits performed, or Pharmatech did not use consultants who lived outside of that state, because of the restrictions. Some states, when you flew in, you would have to go into quarantine for a week or something like that before you could then go out, and so they just had a practice that they had you do work within your state. So that went on for a while during the pandemic.
Q. What about 2022, what percentage of your work came from Pharmatech?
A. About -- or InCompliance?
Q. Um-hum.
A. I would say maybe 75 percent.
Q. And does InCompliance have any employees other than you?
A. No.
Q. Is it an LLC?
A. No.
Q. What is it?
A. I just -- just my own sole proprietor.
Q. Is it incorporated?
A. No.
Q. And what would you say -- what would you estimate the income was of InCompliance in 2022?

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A. Oh, my goodness. I don't know for sure. We're just starting to get 1099s. Um --
MR. SLATER: I have an objection. Why is this relevant? This is confidential financial information of her business. I was slow on the draw in you asking her salary, but I don't see why this is something that she would need to answer, how much money she makes in her private business.
Q. Please go ahead and answer.
DI MR. SLATER: No, I'm asking her not to answer. If you want to explain to me why that's a proper question, I'll certainly listen to you. But I don't know that you are allowed to ask somebody all --
MS. MILLER: You're instructing her not to answer?
MR. SLATER: For the time being unless you want to explain to me what I'm missing.
MS. MILLER: She's working in the pharma industry. This is a pharma case, Adam. It's totally an appropriate question. You can't object on relevancy, you can only object on privilege.
MR. SLATER: I can actually object on, it's her confidential financial information, which I don't think you have a right to, so I'm going to

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direct her not to answer. Please go to the next question.
I don't have any idea how this is something that relates to the issues in the case. You can ask her what she gets paid as an expert witness, and we're going to mark confidential what her salary is, because that's nobody's business.
Q. Do you know whether you earn more from InCompliance than you do from U.S.C. or list?
A. I'm sorry, can you repeat?
Q. Do you know whether you earn more from InCompliance per year than you do from U.S.C., or less?
DI MR. SLATER: Don't answer the question. It's the same issue.
MS. MILLER: We'll have to take it up with the court. If you don't answer today, then we'll have to likely come back, and --
MR. SLATER: Jessica, you don't need to threaten us. Just please proceed with the deposition.
MS. MILLER: I am proceeding with the deposition, Adam, thanks.
Q. Is your company based in your house?
A. Yes, it is.

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Q. How many hours did you spend on your work with Tissue-Tek in 2022?
A. I have no way of knowing without looking back at all my invoices.
Q. Approximately.
A. Again, I could not -- I could not but begin to guess, even venture a guess on that.
Q. Is it more time or less time than you spend at U.S.C.?
A. Less time.
Q. Is it about half as much?
A. I, again, it's -- I'm going to say it's less than half. But again, you know, I do this work on the weekends, in the evenings. Not during work hours. So it's -- it's really difficult to say.
Q. If you don't do it during work hours, how do you visit sites?
A. I take vacation time or as I said, I only go into the office two days a week. And because we work on the weekends, we have a couple of days each week that are our discretionary. So --
Q. I understand that. I just, you had said, I thought a minute ago that you only do this on weekends and evenings, so I was confused.
A. Well, if there's travel involved, if I

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have to go to the firm and if they are not working on the weekend, then I'm going during the week. And as I say, I can use vacation time or I use our -- my weekend, which ends up being weekdays.
Q. And approximately how many clients did you have in 2022?
A. I'm going to say that it was only two because Pharmatech was the major.
Q. Pharmatech and what's the other one?
A. Oak Tree Engineering.
Q. How many different companies is your estimate that you worked for through Pharmatech in 2022?
A. I'm going to say three or four.
Q. Do you know -- and two of those you mentioned the names and the other two you can't recall the names sitting here today?
A. I didn't -- I didn't use -- Tissue-Tek was not in 2022.
Q. Oh, I see. So in 2022, do you recall the names of any pharmaceutical companies that you conducted work with through Pharmatech? I think you said you were getting 1099s, so that might help you remember.
A. I haven't gotten a 1099 or looked at a

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1099 yet from them. And that -- my 1099s from them just give you a total -- a total amount anyway. But one of the firms is located in Canada, and they are involved in managing clinical trials. So not a pharmaceutical company, per se. I audited them.
Q. Do you know the name?
A. Again, I can look it up.
Q. Okay.
A. And I'll do that, that's fine. And then I audited a firm in Italy. Again, I'll look it up.
Q. What do they do?
A. They manufacture drugs and biologics.
Q. And when you say you audited them, what did that entail?
A. Performed a GMP audit.
Q. And the purpose was to determine if they had any violations?
A. I would say I -- violations, well, we don't refer to them as violations. What -- and I say "we" because there was another gentleman who went on the audit as well. But we actually produced a report to them on our findings that would, you know, be areas that they could work on improving.
Q. Do you recall what some of those areas were?

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MR. SLATER: If this is confidential then --
A. I cannot -- yes, that is confidential.
Q. Okay. And what are the third and fourth companies?
A. So one was AccuLab -- and I said I need to look up the facility in Canada that manages clinical trials. There is the company in Italy, and then Oak Tree.
Q. You said Oak Tree was separate from --
A. Oak Tree is separate --
Q. Right. I'm sorry, you said there were three to four companies through Pharmatech, and I've got the Canadian one which you don't remember the name, the Italian one you don't remember the name, AccuLab, and do you remember the fourth name?
A. I don't know that there was a fourth. It was three or four.
Q. Okay. And did you go to Italy to conduct audits?
A. I did.
Q. Oh, that's fun. And do you remember what kind of drugs they make, or biologics?
A. Again, I need to look it up because they make a number of drugs. Not all are prescriptions.

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Some are O/T, over-the-counter.
The biologic area was an area that is new for them, and that's why they wanted some outside assessment.
Q. What types of biologics?
A. I honestly don't know. It was a product that they were developing. So they just wanted some input. And I don't know if it's -- if that product is even on the market. I don't know.
Q. And you said you went to the audit with someone else?
A. Yes.
Q. And why are there two of you?
A. Because of the amount of information and it was a drug and a biologic. And it was best use of time. It was for an inspection, and it's expensive. So we just divide the audit and each take an area.
Q. When you say you each take an area, do you mean a physical area or like a substantive area?
A. Substantive.
Q. And what's your area?
A. For that particular audit, um -- what did I look at? Again, you know, you have to give me time to go back and look, because we ultimately merge a report and we're involved with each other's

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information all the way through. So I would have to go back and look at my notes to see what particular area I audited. Because sometimes there is a bit of crossover.
Q. What part of 2022 was that?
A. I went to Italy in June, I believe.
Q. And you don't recall from June what was your portion of the audit?
A. I don't remember which area specifically I audited for sure, no.
Q. And what did you do for Oak Tree Engineering?
A. I wrote a 510(k) submission.
Q. For what kind of a product?
A. A spinal implant.
Q. Did they get clearance?
A. I'm sorry?
Q. Did they get clearance?
A. Yes.
Q. When was that?
A. We got final clearance in December, I believe it was.
Q. When did you work for Tissue-Tek?
A. What year?
Q. Um-hum?

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A. It was before the pandemic. I'm not sure exactly. Maybe 2019, possibly. I'm not sure.
Q. And were you doing --
A. I'm sorry?
Q. -- and what were you doing for them?
A. The same thing. Went and did a gap assessment audit. And then helped them write some procedures.
Q. Do you know if they subsequently had a recall?
A. No, I don't.
Q. Did your work involve the biologic corneal bandage?
A. We assess the overall quality system.
Q. The quality system of what?
A. Of the manufacturing site.
Q. And where is the manufacturing site?
A. In Florida.
Q. Have they ever been found to have CGMP violations?
A. I'm not sure. I did not look up their history.
Q. Do you generally look up the history of a company's FDA interactions, warning letters, 483s, etc., before agreeing to take that company on as a

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client?
A. No.
Q. Okay. Did lawyers help write your resume?
A. No.
Q. In any of your roles prior to this litigation, have you worked with, in anything involving nitrosamines?
A. No.
Q. Have you done any work prior to this litigation with respect to Valsartan?
A. No.
Q. Is that a Master's degree in public product quality?
A. The MS degree that we have at U.S.C.?
Q. Um-hum.
A. It's medical product quality, yes.
Q. And so you're responsible for the students who have courses seeking MS in that topic?
A. I'm responsible for the program, or the Master's degree program overall.
Q. And is that mostly a weekend program?
A. Yes.
Q. Weekends and nights?
A. Yes, weekends, yes.

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Q. Is your whole program involving people who are working?
A. We have -- I don't know. I want to say possibly now maybe 30 to 50 percent of our students are working professionals.
Q. Um-hum.
A. Possibly more because we have some that are working on internships. So that would drive the number even higher. But the program was originally designed for working professionals, yes.
Q. Have you ever been disciplined in the job?
A. At U.S.C.?
Q. Ever.
A. Only the time we talked about in 1985-ish.
Q. Were you disciplined before you were terminated?
A. No.
Q. Have you ever filed a lawsuit?
A. Um -- I went to Small Claims Court. That's not a lawsuit, right? I don't guess.
Q. What did that involve?
A. It involved a company that I left and they paid me electronically and then they took it

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back after I resigned.
Q. What company was that?
A. MedCell Biologics. MedCell Biologics.
Q. When was that?
A. It was before I was at the FDA. It was very short-term. It was -- the reason left was because the drive was -- it was down in San Diego. I was only there a couple of months -- excuse me, that is not true. That is not the name of the company, that is not true. That was another time I worked in San Diego. It was MedCell. When I was there previously was -- oh, my goodness, again only a couple of months for the same reason. And that I would say was 1993-ish for couple of months. Yeah, something like that.
The name of the company -- I'll look it up during the break. I don't recall the name of the company. It was just a couple of months. So not on my radar.
Q. I'm totally confused. You worked at Medcell, but that's not the company that you sued?
A. No. No, it is not the company.
Q. When did you work at Medcell? 'Cause it's that not on your resume --
A. Yeah, you know, I honestly don't have it

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on my resume, because it was only a very few months because as I say the drive was too much.
Q. But that's not the company you sued?
A. No.
Q. So what's the company you sued?
A. That's what I'm trying to recollect their name. That was in -- that was -- again, I'm going -- I'll look it up. I've got it somewhere.
Q. Is the company that you sued on your resume?
A. No.
Q. How long did you work at the company you sued?
A. Less than three months.
Q. So you have two jobs you worked less than a year, Medcell and this company you sued?
A. Um-hum, yes.
Q. And you left Medcell because of the commute. Why did you leave this other company?
A. This same reason.
Q. They both had long commutes?
A. They were both in San Diego.
Q. Which one did you work at first?
A. The one I can't remember the name.
Q. So you left there because it was a long

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commute and then you took another job in San Diego?
A. I did.
Q. And it's your understanding that if you're at a job less than a year it doesn't need to go on your resume?
MR. SLATER: Objection, argumentative. Is there some standard you're quoting? I'm not sure what you're asking.
Q. Go ahead.
A. You're asking me? What did you ask me?
Q. What's the minimum time job that you believe has to go on a resume?
A. I've never really considered that.
Q. So other than MedCell Biologics, the company that you don't recall the name of, and the company that terminated you, are there any other jobs you've had that aren't on your resume?
A. Not that I recall.
Q. Are you on social media?
A. I have a Facebook page.
Q. For professional purposes?
A. I'm sorry?
Q. Do you use that for professional purposes or only personal?
A. Personal. I do also have a LinkedIn

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profile.
Q. What's your name on LinkedIn?
A. Susan Bain.
Q. And how about on phase book?
A. Susan Bain.
Q. You said you were first contacted about this litigation, I think you said April or May 2022 by Chris Geddis, is that correct?
A. Yes, to my recollection.
Q. And when did you agree to serve as an expert, or did you agree right away?
A. In that same time frame.
Q. Was it one call in which you agreed or was it later?
A. I believe correspondence was via e-mail.
Q. Um-hum.
A. So we had several e-mails back and forth.
Q. So it was approximately a week or -- approximately how much time between when you were first contacted and when you agreed to serve as an expert?
A. Maybe one to two weeks.
Q. Okay. And did you review any materials during that one to two weeks --

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A. No.
Q. -- before agreeing to serve as an expert?
A. No, I did not.
Q. Your expert report has a lot of deposition summaries in it, correct?
A. Yes.
Q. Did you write those?
DI MR. SLATER: Objection, don't answer the question. Next question.
Q. Did anyone other than your lawyers help you write your report?
DI MR. SLATER: Objection to the way the question was framed. Can you reask the question, please? I wouldn't object if you say, "Did anybody other than an attorney." "Putting aside attorney, did anybody who is not an attorney assist you with writing your report?" That question I will not object to.
Q. How did you decide what information to include in your report from depositions?
DI MR. SLATER: Objection. You're asking the same question in different ways.
MS. MILLER: It's a really different question.

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MR. SLATER: It's not, though, because it a goes to decisionmaking and drafting of the report and that's not an area that you're supposed to ask about, just like it's not an area that we're going to ask your experts about because we're going to respect the rules as well.
MS. MILLER: I'm asking the expert how she decided what information include and what information to exclude. Goes to her methodology, Adam. It's an appropriate question.
Q. Can you tell me how you decided which information from the depositions to include in your report?
MR. SLATER: All right, I'll let you answer that, go ahead.
MS. MILLER: That was the same question.
MR. SLATER: I'm sorry, are you laughing? Was something funny? I missed the joke.
MS. MILLER: Adam, Adam.
THE WITNESS: Can you repeat, please?
MS. MILLER: Sure. Court reporter, can you repeat the question.
(Record read.)
A. So I included information that I felt was germane to the topic at hand.

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Q. The topic at hand being what?
A. GMP violations.
Q. Did you include all information that was relevant to whether or not there were GMP violations?
A. No, I did not.
Q. So was there some information or testimony in the depositions related to whether there were CGMP violations that you did not include in your summaries?
A. Yes.
Q. How long did it take you to read and summarize each deposition?
A. Well, the -- that's hard to say. The depositions were different lengths.
Q. Um-hum. So I'm --
A. Some depositions had, you know, more information that I felt was germane. So approximately how long? Three or four hours? Some more, I mean, some of the depositions were quite voluminous, as you saw, hundreds of pages, so those obviously took longer.
Q. When did you first speak with Adam Slater?
A. Oh, my goodness. I would say very early on, mid-May, early May, mid-May.

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Q. Have you met any of the Plaintiffs' lawyers in person?
A. No.
Q. Approximately how many times since April have you spoken with Plaintiffs' counsel?
A. Oh, my goodness. I -- I don't know that I could answer that. Are you saying verbally or via e-mail?
Q. That was verbally.
A. Verbally. I don't know.
MR. SLATER: You're allowed to estimate or approximate.
A. Approximate, oh, fifty times, less, you know, 30, 40 times.
Q. Were you familiar with Valsartan at the time that you were contacted by Plaintiffs' counsel?
A. Yes.
Q. What was your basis of familiarity?
A. I took Valsartan.
Q. Did you take Valsartan during the period at issue in this litigation?
A. Yes.
Q. What did you do at the time of the recall?
A. Nothing, honestly.

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Q. What do you mean by that?
A. I kept taking medication and I was never contacted by my pharmacist to tell me that I was taking product that was under a recall.
Q. Did you see it on the TV or something?
A. The recall? I honestly don't know where I saw it. I don't -- because I receive recall notices because of my work at school. I receive recall notices from, you know, various professional organizations that I belong to that, you know, they will forward them and, you know, things of that nature.
So I can't say if I read it or I saw it on TV. As a matter of fact, I didn't even know -- as I sit here, I don't know that it was on TV. But I would have become aware via reading it most likely.
Q. How soon after the recall did you become aware of it?
A. I, again, don't know.
Q. Did you finish the Valsartan bottle you had in your home?
A. I took the Valsartan that I had. I -- as I said, I was never notified that I actually had anything that was under recall.
Q. And once Valsartan was recalled, did you

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switch to another medication?
A. No.
Q. You were able to get Valsartan all the way through?
A. Yes.
Q. Have you ever asked a physician or pharmacist whether you had taken Valsartan that was recalled?
A. No.
Q. Have you ever asked your doctor about any potential risk from having taken Valsartan?
A. No.
Q. Were you familiar with ZHP as a company at the time you were contacted by Plaintiffs' counsel?
A. No.
Q. You had never heard of ZHP?
A. No, I had not.
Q. Had you heard of Prinston or --
A. No.
Q. -- Solco?
A. No.
Q. Prior for this litigation, did you ever do any consulting work involving Valsartan or nitrosamines?

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A. No, I did not.
Q. Do you know whether NDMA or NDEA has ever been found in Valsartan or Exforge?
A. To my knowledge, there's never been a confirmation that it's been found in either Exforge or Diovan.
Q. And what do you mean by, there's never been confirmation?
A. My understanding is that at one time, there was a claim made that there was some NDMA in the product, the Diovan product. However, it to my knowledge was not confirmed.
Q. When you say some claim, who made that claim?
A. I don't -- I don't recall.
Q. Did you revise your resume in advance of this litigation or did you just provide a prior resume?
A. Provided a prior resume.
Q. Would any of your opinions change if it were confirmed that NDMA was found in Diovan or Exforge?
A. That's awfully hypothetical.
Q. Correct. We ask hypotheticals at depositions.

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A. I think it would depend on the facts. I would really honestly need to see the -- the testing and the overall, the work that was done at the manufacturer to really understand. I don't know that I could understand without seeing it and -- that's a hypothetical that's really outside of what I -- what I have considered.
Q. I'm asking you to consider it now. Can you think of any opinions that you've offered in this litigation that would be changed if the RLD -- you know, that means Reference Listed Drug, I assume -- were found to have contained NDMA or NDEA?
MR. SLATER: Are you asking if it was found on testing or are you saying if it was part of the formulation and the specifications as being part of the formula?
MS. MILLER: Adam, I asked my question. Lets have the witness answer it.
MR. SLATER: I object to the question.
You can answer.
MS. MILLER: Do you need the question repeated to you?
THE WITNESS: No, I don't need the question repeated.
MS. MILLER: Okay.

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Q. So go ahead.
A. Are you asking if the RLD was approved with an impurity, being NDMA?
Q. I'm asking whether, if it is confirmed that Diovan or Exforge was tested and found to have NDMA, would that change any of your opinions that you're offering in your report?
MR. SLATER: Objection. The question is -- lacks foundation.
MS. MILLER: It's a hypothetical.
MR. SLATER: I understand. It still lacks foundation. It's very imprecise and ambiguous. You didn't answer her question when she sought to clarify what you're actually asking, which you're refusing to tell her what your question actually means, on top the inadequacies of the question to begin with. I object.
I'm not going to stop her from answering, but there are serious problems with the question that I've placed on the record. I'm not sure why we're smiling but it's okay.
Q. Please go ahead.
A. My opinions would not change.
Q. What did you know about NDMA and NDEA before agreeing to serve as an expert in this litigation?
A. I didn't know anything about it other than what I had heard about the recall of Valsartan.
Q. Did you know anything about DMF --
A. No.
Q. -- before agreeing to serve in this litigation?
A. No.
MR. SLATER: You're talking about the solvent, not DMF, the regulatory document, right?
MS. MILLER: I think we understood each other, right?
MR. SLATER: I don't understand why you can't answer. It's just being polite.
MS. MILLER: I don't think it's your job here to ask questions. I think it's my job to ask questions, so I'm going to ask the question --
MR. SLATER: All right, thank you for your politeness. I appreciate it.
Q. Have you ever done any consulting work in connection with a product that contained NDMA or NDEA?
A. No, I haven't.
Q. Have you ever advised a client on any risks related to NDMA or NDEA?

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A. No, I haven't.
Q. Do you know how many different types of nitrosamines there are?
A. No.
Q. Do you know how many types of nitrosamines can be found as impurities in pharmaceuticals?
A. No, I don't.
Q. Do you know how often nitrosamines have been found in pharmaceuticals?
A. No.
Q. Have you ever worked with the solvent, DMF?
A. No, I have not.
Q. When did you first hear the term DMF as a solvent?
A. As part of this litigation.
Q. Do you know whether any of the companies that you've ever worked with used DMF?
A. I can't say definitively, but not that I recall.
Q. Do you know whether any of the companies that you have done work with have used a testing method known as GCFID?
A. Companies I've worked with?

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Q. Or consulted for.
A. They've had GC, but I don't know if it was FID.
Q. When you say you don't know if it was FID, can you explain?
A. When I would do an audit of the lab, they would just say, "This is our GC machine, instrument." So whether they -- anything beyond that, I don't know.
Q. Have you ever advised a client or company on whether GCFID testing was appropriate for their operations?
A. No, I haven't.
Q. Prior to being contacted to serve as an expert in this litigation, did you know whether the TA manufacturing process could lead to the formation of NDEA?
A. No, I did not.
Q. Before you were contacted by Plaintiffs to serve in this litigations, did you ever make any public statements about whether Valsartan was adulterated?
A. No.
Q. Prior to being contacted about serving as an expert in this litigation, did you have any

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opinions about whether the manufacturing process for Valsartan could lead to the formation of NDMA?
A. Could you please repeat?
MS. MILLER: Court reporter, did you get it? Why don't you repeat it. I always worry, if I repeat it, I'll change a word or something.
(Record read.)
A. No.
Q. Do you have any research assistants?
A. No, I do not.
Q. Did you perform any literature searches to prepare your report?
A. I've reviewed literature, yes.
Q. Was that literature provided to you by Plaintiffs' counsel?
A. Yes.
Q. Did you review any literature that was not provided to you by Plaintiffs' counsel?
A. I did some research on the manufacturing practices and some of the GMP foundations.
Q. Can you explain what that research entailed?
A. I just went back into the FDA website and looked at definitions like for, you know, adulteration and a few other things. I reviewed the

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ICH guidelines, I reviewed the some of the FDA guidance documents. That's all I recall.
Q. Everything else that you reviewed was provided by Plaintiffs' counsel?
A. I believe so.
Q. You wrote in your report that you reviewed corporate documents, including e-mails, reports, SMPs and similar internal protocols. Fair to say you got those from Plaintiffs' counsel?
A. Yes.
Q. And did you select those documents from a database or were they just provided to you?
A. They were provided to me.
Q. Do you know how many documents were produced in this litigation?
A. To me or the overall litigation?
Q. Do you know how many documents ZHP has produced in this litigation?
A. I have no idea.
Q. Do you know what percentage of documents proceeded by ZHP in the litigation you've reviewed?
A. I have no idea.
Q. Your reliance list cites 2023 ZHP documents on it. Were those all selected for your review by Plaintiffs' counsel?

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MR. SLATER: Objection, lack of foundation.
You can answer. Just so you understand the objection, Dr. Bain, I'm just saying I'm not sure that the number she counted is correct because there's a supplemental list or whatever, but that was my only issue.
A. No, they were not -- yes, everything that's on that list was provided to me by counsel.
Q. Do you know whether you received all of the ZHP SMPs and internal protocols?
A. I do not know.
Q. Did you take notes while reviewing those materials?
A. I just had, you know, some general highlights and some personal thoughts. But other than that, no.
Q. Do you still have the documents with the general highlights and personal thoughts on them?
A. No.
Q. What happened to them?
A. I deleted.
Q. Why did you delete them?
A. I didn't need them any longer.
Q. Do you read Chinese?

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A. I'm sorry?
Q. Do you read Chinese?
A. No.
Q. When did you delete those documents?
A. After I wrote my report, I believe.
Q. And were your notes with pen or were they highlighted on the laptop?
A. Highlighted on the laptop.
Q. Did someone instruct you to delete them?
A. No.
Q. Did you review any scientific literature?
A. Just the scientific literature that was provided.
Q. Provided by whom?
A. Counsel.
Q. Did you take any notes on those before deleting them?
A. No.
MR. SLATER: Objection, lack of foundation.
Q. How did you identify which employee depositions to review?
A. I was provided the depositions.
Q. Do you know if you were provided all the

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depositions?
A. No, I do not.
Q. Did you speak to anyone at the FDA in the course of preparing your report?
A. No.
Q. Did you review drafts of the Hecht or Plunkett reports?
A. I don't remember reviewing a Plunkett report. Drafts, I don't believe I read any draft reports.
Q. Do you think you're qualified to offer an opinion on how nitrosamines form?
MR. SLATER: Objection, argumentative.
You can answer.
A. I'm not an organic chemist. So if you're asking about chemistry, no. I'm not an expert in that area.
Q. There is some discussion of chemistry in your report, correct?
A. Correct.
Q. Is that all based on Dr. Hecht's report?
A. Dr. Hecht's report and some of the literature that was cited.
Q. When you state that the foreseeable chemical reactions in the process were well

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understood by organic chemists in the scientific community, are you relying on Dr. Hecht for that?
A. Dr. Hecht's report, and Dr. Najafi, and some of the literature that I looked at, the IARC monograph where it states that it's -- the formation of NDMA has been known since 1865.
Q. Does the IARC monograph address the same circumstances in which Valsartan was manufactured?
MR. SLATER: Objection. You can answer.
A. It talks about the formation of nitrosamines.
Q. Are you offering an opinion that the IARC monograph should have put ZHP on notice that its manufacturing processes would have led to the formation of nitrosamines?
A. No.
Q. And when you say "the scientific literature," are you simply referring to scientific literature that was provided to you by Plaintiffs' counsel?
A. Yes.
Q. Do you feel qualified to determine, based on those two scientific articles, I think one was an excerpt from a textbook and one was an article, as to whether ZHP should have been on notice

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that its manufacturing process would lead to the formation of nitrosamines?
MR. SLATER: Objection, lack of foundation, mischaracterization of the record.
You can answer.
A. That was awfully long, could you please read that back?
MS. MILLER: Sure. David, go ahead.
(Record read.)
A. I'm sorry, on notice by whom?
Q. I think my question was whether it would have put ZHP on notice. ZHP is the Defendant.
A. So based on the literature having been put on notice, who would put them on notice? I guess I'm not understanding the question.
Q. Is it your opinion that ZHP should have known based on the two articles, one is an article, and one is a textbook excerpt provided to you by Plaintiff's counsel, that those two documents should have led ZHP to know that the manufacturing process it was using could have led the formation of nitrosamines?
MR. SLATER: Same objection, lack of foundation, mischaracterization of the record.
You can answer.

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A. Based on the reports of Dr. -- Drs. Hecht and Najafi, it's my feeling that this reaction is something that is covered or well understood in the organic chemistry field. So if you're asking whether I think ZHP should have known, I would say yes.
Q. Did you personally test Dr. Najafi and Dr. Hecht's opinions or did you simply assume they were correct?
MR. SLATER: Objection, you can answer.
A. I did not test their opinions. I merely read the literature citings.
Q. If Dr. Hecht and Najafi are wrong, would that affect your opinions in this litigation?
MR. SLATER: Objection.
You can answer.
A. If their opinions are wrong, that would also go to the literature they cited as being wrong as well.
Q. Did the literature they cite discuss the same manufacturing process used by ZHP?
MR. SLATER: Objection.
You can answer.
A. That's my understanding.
Q. Was DMF heated to the boiling point

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during the ZHP manufacturing process?
A. I remember reading the temperature that it was heated to. I also remember reading boiling point. But I don't know the boiling point of that particular process without -- if I could be pointed to that -- to that area of a document that talks about the manufacturing.
Q. Was it known in 2011 that DMF could degrade if it wasn't heated to boiling point?
MR. SLATER: Objection.
You can answer.
A. Yes. That would -- as I understand, yes.
Q. And can you tell me sitting here what scientific literature you would cite for the proposition that DMF -- that it was known to the scientific community in 2011 that DMF could degrade if it wasn't heated to boiling point?
A. Can I speak for the whole scientific community? I can speak to what literature was out there.
Q. Let me ask my question different --
MR. SLATER: I'm sorry, were you still answering the question?
MS. MILLER: I think she misunderstood

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the question --
MR. SLATER: The point is, I'm trying to ask if she has finished speaking. I thought she might have been interrupted. If I misunderstood, it's okay. I just want to make sure that we don't interrupt an answer in the middles.
THE WITNESS: I was finished.
Q. Let me try and ask the question differently. What are you relying on, what scientific literature are you relying on for the belief that it was known in the scientific community in 2011 that DMF could degrade below the boiling point?
A. Dr. Hecht and Najafi's reports, the IARC monographs. I'm not sure if, you know, again, the whole scientific community, who reads what documents or what literature. This I'm not sure.
Q. Does the IARC monograph discuss whether DMF can degrade below the boiling point?
A. I would need to pull it up and look at it.
Q. Do you recall reading any scientific literature that said DMF could degrade below the boiling point?
A. I don't remember.

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Q. Is it your opinion that it was well understood by organic chemists in the scientific community in 2011 that DMF could degrade below the boiling point?
A. This was my understanding, yes.
Q. And is that understanding based on your own investigation or is that understanding based on Dr. Hecht and Dr. Najafi?
A. It is based on Dr. Hecht and Dr. Najafi.
Q. If Dr. Hecht and Dr. Najafi are wrong and it wasn't well understood in the scientific community that DMF could degrade below the boiling point in 2011, would that change any of your opinions in this litigation?
A. No.
Q. Can you explain to me how the zinc chloride process used by ZHP resulted in the formation of NDMA?
A. I'm sorry, you're asking for chemical reactions?
Q. Do you know how that happened?
A. The -- I can only tell you the basics because, again, I'm not an organic chemist. But DMF decomposes to DMA. Then that's -- that reacts with -- in the -- with sodium nitrite to form the

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NDMA.
Q. Have you read Dr. Xue's report, X-u-e?
A. I don't recall.
Q. Do you recall reading a report by a professor of organic chemistry in the University of Maryland?
A. I don't recall.
MS. MILLER: I must take a five-minute break to get a drink so let's go off the record.
VIDEOGRAPHER: The time is 9:01. We're going off the record.
(Recess taken.)
VIDEOGRAPHER: The time is 9:21. This begins media number 3. We're back on the record.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. Did you talk to your counsel during the break?
MR. SLATER: I'm going to tell you I'm objecting to discussions with the experts between breaks. I assume you don't want us asking your experts whether they discussed anything with you during breaks, either. I never ask those questions, I've never seen the questions asked except in this litigation, so I'm not really sure what you're

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getting into, but I would assume everybody should be not asking those questions. And I think it's work product.
MS. MILLER: I was not asking what you discussed. What you discussed would be work product. Whether you had a discussion is not.
MR. SLATER: I agree with that.
MS. MILLER: That's what I asked.
MR. SLATER: Okay, I figured you were going to the next place.
MS. MILLER: I'm sorry, you were objecting to the next question I haven't asked?
Q. I was just asking if you spoke with your counsel during the break?
A. Yes, I did.
Q. For how many minutes?
A. Five minutes, approximately.
Q. Before we went on the break -- and I apologize, my throat is really starting to go -- but before we went on the break, we were talking about your report.
You also state in your report that the technical means to test and determine whether nitrosamines were formed during the Valsartan manufacturing process were readily available in 2011.

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Do you recall that?
A. Yes.
Q. And is that also based on statements by Plaintiffs' experts?
A. Yes.
Q. Do you personally have the knowledge to know whether the technical means to test and determine whether nitrosamines were formed in the manufacturing process for ZHP were readily available in 2011?
A. I believe it was Dr. Li's testimony. He said that they -- he -- excuse me. He had used the GCMS methodology to test nitrosamines back as early as, I believe it was 2008, that time frame.
Q. So is this opinion based solely on the opinions of Dr. Li?
A. As well as the reports of Dr. Hecht and Najafi.
Q. Did the FDA believe that the technical means to test and detect whether nitrosamines had formed was readily available in 2011?
A. All I could point to there is the warning letter where they said that ZHP was in violation.
Q. Do you know whether the FDA believed

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that the technical means to test and determine whether nitrosamines were formed were readily available in 2011?
A. Their inspections were -- I don't know about inspections performed prior, in that time frame. In 2018, they did feel the technology was available.
Q. When did the FDA begin to develop a test to detect and quantify NDMA in Valsartan?
A. I don't know that.
Q. Did the FDA believe that NDMA's properties make it difficult to find?
MR. SLATER: Objection.
You can answer.
A. The FDA, in their warning letter in 2018, stated that ZHP was responsible for the finished quality product -- finished quality, I'm sorry.
Q. That doesn't really answer my question. My question was, do you know whether the FDA believed that NDMA's properties make it difficult to find?
MR. SLATER: Objection.
You can answer.
A. Whether FDA thinks that? The only reference that I am aware of was in their press

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release. And other than that, I have no way of knowing.
Q. Did the FDA state in this press release that NDMA's properties make it difficult to find?
A. You know, can we pull that up, please?
Q. We're going to pull it up in a minute. I just want to know whether the FDA said that.
MR. SLATER: She's asked to see the document. I'm not sure --
MS. MILLER: -- I'm just -- minus the e-mail, sitting here today --
MR. SLATER: But she's said she needs to see the document to answer the question. So can we please get the document.
Q. Do you know whether the FDA has said that NDMA's properties make it difficult to find?
MR. SLATER: I'm sorry, you can't just bulldoze. The witness asked to see the document.
MS. MILLER: I will show this document --
MR. SLATER: So show it.
MS. MILLER: -- the witness knows --
MR. SLATER: She asked to see the document.
Q. Has the FDA ever said that NDMA's

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properties make it difficult to find?
MR. SLATER: Same objection.
You can answer as best you can, or do whatever you need to do to answer.
A. There was a statement similar to that. And again, without seeing the document, I don't know the statement verbatim. But there was a statement to that effect, but again, I'd like to see the document to see the exact verbiage used.
Q. Is the FDA responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nations's food supply, cosmetics and products that emit radiation?
A. Yes.
Q. Do you agree that the FDA is considered to be the most advanced regulatory system around the world with a staff of approximately fifteen thousand employees and an annual budget of $5.1 billion?
MR. SLATER: Objection.
You can answer.
A. Yes.
Q. You mentioned a press release a moment ago from the FDA.

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A. Yes.
Q. Was that included in your original reliance list?
A. I would have to go back and look.
Q. Are you aware that your counsel produced a supplemental list of documents reviewed earlier this week?
A. Yes.
Q. Are you aware that the FDA press release was included there and not on your original reliance list?
A. Again, I'd have to go back and look. It was quite an extensive list.
Q. Do you know why the FDA press release was not included on your original reliance list?
A. I don't know that answer.
Q. When did you read the FDA press release?
A. Again, I can't tell you when I first saw this press release.
Q. Did you read the press release before you wrote your report?
A. I'm not sure.
Q. Did you read the press release for the first time last week?
A. No.

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Q. Did you first see the press release after submitting your report?
A. I don't remember at what point I saw the press release.
Q. If it wasn't cited in your report, and it wasn't in your original reliance list, does that mean you didn't read it before you wrote your report?
A. Not necessarily.
Q. Are there materials that you reviewed and considered that were not included in your original list of materials considered?
A. Yes.
Q. What materials are those?
A. I can't tell you off the top of my head. You know, we'd have to go back, collect one by one and look.
Q. But sitting here today, you don't know whether you read the press release before you wrote your report or after you wrote your report; that's your testimony?
A. That is my testimony.
Q. And what about the two FDA statements that the FDA released, you're aware that the FDA released two statements between July 2018 and January 2019 about the discovery of nitrosamines in

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Valsartan, correct?
MR. SLATER: Objection, foundation. Are we saying the press release is different than the statements? I just, I need to understand for purposes of understanding the question because I thought we were talking about the same thing.
THE WITNESS: As do I.
Q. You added to your supplemental reliance list a press release and two statements by the FDA, correct?
A. Can I see the list, please?
Q. Did you put together your supplemental --
MR. SLATER: Sorry, this is the second time she's asked to see a document. I'm not sure why it is that you won't show the document.
And, Doctor, you're allowed to consult it. If you have it, you can go look for it if you need to answer the question. They can't stop you from looking at something.
Q. Did you put together your supplemental reliance list?
DI MR. SLATER: Objection, don't answer the question. It's work product. Come on.
Q. Are you refusing to answer whether you

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wrote your supplemental --
MR. SLATER: She's taking my instruction not to answer, because it's work product. It's part of the report. It's a supplemental part of her report. It was covered, okay?
Q. Do you recall at the beginning of the deposition I asked you, if you're looking at materials on your computer, to let me know?
A. Yes.
Q. Okay. So if you're looking at materials on your computer, you need to let me know. You can't just look at materials without telling me. That's part of the rules of the deposition, all right?
A. Okay.
MR. SLATER: Objection, let's not be argumentative.
(A pause in the proceedings.)
MS. MILLER: I'm marking as Exhibit 2 a document entitled -- scroll up to the top, Alex, so I can read it -- "Supplemental List of Documents Reviewed," dated January 29, 2023.
EXH (Susan Bain Exhibit 2, document entitled, "Supplemental List of Documents Reviewed," dated 1/29/23, marked for identification, as of this date.)

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Q. Have you seen this document before?
A. Yes.
Q. When did you see it?
A. January 29th.
Q. That was earlier this week, correct?
A. Yes.
Q. All right. Did you read any of the documents on this list before you wrote your report?
A. This is the entire list?
Q. Alex will scroll down.
(A pause in the proceedings.)
MR. PERRY: Is it okay to keep going? Okay. I wasn't sure if you had the whole thing there.
THE WITNESS: Would you scroll back up, please.
(A pause in the proceedings.)
Q. Do you remember the pending question?
A. I don't recall seeing them before I wrote my report. I can't guarantee one hundred percent. For example, regulatory documents, you know, FDA ANDA's impurities and drug substances, I may have seen in an earlier time.
Q. Do you know when you first saw the documents that are 2, 3 and 4 underneath "Regulatory

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Documents"?
A. I can't tell you when I saw those.
Q. How did you obtain them?
A. From counsel.
Q. Do you know when counsel sent them to you?
A. No, I don't.
Q. Did counsel send them to you in the last two weeks?
A. Again, I -- I don't remember.
Q. Did you ask counsel for these additional materials or were they sent to you without requesting them?
A. I honestly don't -- don't remember. 2, 3 and 4, I don't remember.
Q. Did you consider these three materials in forming your opinions that are listed in your report?
A. I'm sorry, can you repeat that?
Q. Did you consider these three documents in forming the opinions that are set forth in your report?
A. You know, if we can, I'd like to pull those up because, just by the titles that are on here, I don't remember the content of each one of

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those.
Q. Understood. But I'm just trying to determine when you read them.
A. Again, I -- I don't remember. I -- there were a number of documents that covered the same types of topics, so I can't tell you exactly when I read these documents.
Q. And you don't know when you received the press release from Plaintiffs' counsel?
A. No.
MS. MILLER: Let's pull up tab 8. We're going to mark as Exhibit 3, FDA press release dated August 30th, 2018.
EXH (Susan Bain Exhibit 3, FDA press release dated 8/30/18, marked for identification, as of this date.)
Q. Does this refresh your recollection as to when you first saw this document?
A. No, I don't remember when I first saw this document.
Q. And you still don't remember whether you first saw it before you wrote your report or after you wrote your report?
A. I do not remember.
Q. Does the fact that it was on your

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supplemental reliance list and not your original reliance list suggest to you that you did not see it before you wrote your report?
A. Not necessarily.
Q. Okay. Does the FDA maintain the most advanced pharmaceutical laboratory of any regulatory agency in the world in St. Louis?
A. I have no way of knowing that.
Q. Do you know whether this is the document in which the FDA stated that NDMA's properties make it difficult to find?
A. Give me a moment to read it, please.
Q. We can show you where that is.
MS. MILLER: Can you highlight it?
MR. SLATER: What page is that on? Because I just happen to have the document here. It's too small. Is it possible to make the documents bigger?
MS. MILLER: Alex has graciously enlarged and highlighted that sentence, can I --
MR. SLATER: What page are you on --
MS. MILLER: It's right here up on the screen, Adam.
MR. SLATER: You know, I'm sorry, do you have to be so impatient with me? I'm really not

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doing anything other than asking if this is on page -- is this 2? Is this on page 1, 2 -- I'm looking at the hard copy, that's why I'm just asking what page it's on. So you could just say, "Page 2."
I found it though. I found it. Page 2, thank you.
Q. Ms. Bain, did I read that correctly?
A. I believe you did.
Q. Do you disagree with the FDA that NDMA's properties make it difficult to find?
MR. SLATER: Objection, you can answer.
A. I believe, given the instrumentation available, that it is easy to find.
Q. So you're disagreeing with the statement.
A. Yes.
Q. And when did the FDA, based this paragraph, develop a testing method to find NDMA in Valsartan? Was it before or after 2011?
A. The next sentence --
Q. Um-hum.
A. -- says that senior scientists have now developed a GCMS method.
Q. So that method was developed after the recall, correct?

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MR. SLATER: Objection.
You can answer.
A. The way this is worded, that's what I would assume.
Q. And that's several years after you say that the technical means to test and determine whether nitrosamines had formed were readily available, correct?
A. Yes.
Q. Do you know whether ZHP ever used GCMS to test for nitrosamines?
A. Yes, them.
Q. And when ZHP used GCMS to test for nitrosamines, did they find nitrosamines?
A. They had unidentified peaks.
Q. Did ZHP use GCMS to determine what those peaks might be?
A. In what time frame?
Q. 2018.
A. In 2018, they did.
Q. And did they find NDMA?
A. Yes, they did.
Q. Was there a time when ZHP used GCMS and did not find NDMA or NDEA?
A. I can't answer that question.

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Q. Do you know whether GCMS testing can find NDMA, regardless of what solvent is used?
A. I can't answer that question.
Q. Do you consider yourself to be an expert on GCMS testing?
A. No, I'm not.
Q. When you say NDMA's properties make it easy to find, are you solely relying on other experts in this litigation?
A. I'm relying on Dr. Hecht's and Najafi's reports, as well as the literature cited.
Q. The literature cited by them?
A. Yes, and in my report.
Q. Do they cite literature for the proposition that NDMA's properties make it easy to find?
A. I would have to go back to their reports and see if they actually said that it was -- the -- used the words, "Easy to find."
Q. Well, you used those words, so I'm just trying to understand, is the basis their reports or is the basis actual literature?
A. The basis is the fact that it's able to be found.
Q. What do you mean?

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A. You run the test, you get the peak, it's there.
Q. Which test?
A. GCMS.
Q. Can it be found with GCFID?
A. I don't know what to answer.
Q. Do you know whether GCFID was an accepted form of testing API between 2010 and 2018?
A. I don't know that answer.
Q. What's the difference between GCMS and GCFID?
A. I don't know.
Q. Can GCFID find NDMA?
MR. SLATER: Objection.
You can answer.
A. As I understand it, GCMS is the most accepted way to find NDMA.
Q. Do you know why GCFID is not always adequate to find NDMA?
A. No, I don't.
Q. If we can go further down to page 3, does the FDA employ organic chemists?
A. I don't know.
Q. Does the FDA have a department of chemistry?

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A. I don't know.
Q. Do organic chemists review Drug Master Files in connection with NDA applications?
A. I don't know who performs the reviews of DMFs.
Q. Do you know how many organic chemists work at the FDA?
A. I don't know.
Q. Have you ever heard of the FDA department of chemistry?
A. No, I haven't.
Q. If we could go to the bottom paragraph that's on the screen starting with the sentence, "Because," could you read that sentence that begins "because"? Alex will highlight and enlarge it.
(A pause in the proceedings.)
Q. Can you read it aloud?
A. "Because it was not anticipated that NDMA would occur at these levels in manufacturing of the Valsartan API, manufacturers would not have been testing for it."
Q. Do you disagree with the FDA that it was not anticipated that NDMA would occur at these levels in the manufacture of the Valsartan API?
MR. SLATER: Objection.

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You can answer.
A. I disagree with the FDA.
Q. And why do you disagree with the FDA?
A. They said in their warning letter that ZHP should have been testing for NDMA and that industry practice is not always consistent with GMP.
Q. If the FDA were correct that it was not anticipated that NDMA would occur at these levels in the manufacture of Valsartan API, would that affect your opinions?
MR. SLATER: Objection.
You can answer.
A. No.
Q. Why not?
A. Pharmaceutical companies are required to perform risk analysis during development and through the entire life cycle of the product, and assess for any kind of genotoxic or carcinogenic --
Q. When was the last time you --
MR. SLATER: Sorry, had you finished your answer?
THE WITNESS: No, I was going to say "impurities."
Q. When was the last time you looked at this press release?

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A. Yesterday.
Q. Did you read it in full yesterday?
A. Yes.
MS. MILLER: Can we go to the top of the page. Top of page 3.
Q. Under the "Agency's Longstanding Policies," that paragraph. Can you read the last sentence of this paragraph.
A. "We employ robust teams of organic chemists as part of our newly-established Office of Pharmaceutical Quality to review applications and referenced information, to look for steps and manufacturing changes where these risks could be introduced."
Q. Does this refresh your recollection as to whether the FDA has organic chemists?
A. It says so in the press release, so I would have to testify that when this press release was written, they must have had a team of organic chemists.
Q. Did those organic chemists ever raise concern that they believed that the Valsartan manufacturing process could lead to the degradation of DMF and ultimately the formation of NDMA prior to the recall?

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MR. SLATER: Objection. Just to clarify, are you talking about chemists in the newly-established Office of Pharmaceutical Quality, or other chemists, and during what time frame? It's very unclear.
Q. Please go ahead and answer.
A. I don't have any knowledge of the organic chemists at that time raising any question or any concerns regarding NDMA formation.
Q. Do you agree with the FDA that risk to the patients who took Valsartan with nitrosamine impurities is very low?
MR. SLATER: Objection.
Answer.
A. I have no way of knowing.
Q. Are you concerned about your health as a result of taking Valsartan?
DI MR. SLATER: Objection, don't answer the question. You're not going to ask her about her personal medical condition. You can go to the judge if you want on that.
Next question.
Q. Do you recall whether in any of these statements from the FDA, they quantified the level of potential risks from using Valsartan that had NDMA or

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NDEA impurities?
MR. SLATER: I just have an objection to ask how this is part of this deposition. That sounds like general causation testimony. I'm being serious. I mean, it sounds like a general causation questioning and I don't think that's part of this deposition. Just curious how it's part of this.
I withdraw the objection. You can answer.
Actually, I'm going to stand the objection, but you can answer. I'm going to keep the objection, but you can answer.
A. Could you repeat the question now?
MS. MILLER: Court reporter, please go ahead.
(Record read.)
A. Are you talking about, when you say, "Statements," are you referring to the press release?
Q. I'm referring to items 3 -- I think it was 3, 4 and 5 on your supplemental reliance list that we were just talking about, those three statements from the FDA. One is called a press release, and two are called statements. I'm just using the FDA's terminology.
A. I'd like to look at them because I don't

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recall if there's anything in those that specifically say at what level Valsartan is going to affect someone's health.
Q. At any time prior to 2018, did the FDA ever state that manufacturers should be using GCMS to test medications for nitrosamines?
A. I'm unaware that FDA ever told industry what instrumentation or test methods to use for identification of NDMA.
Q. Prior to 2018, did the FDA ever tell any API manufacturers that they should not be using GCFID testing?
A. I have no way of knowing what FDA told individual manufacturers regarding test methods.
Q. Are you aware of any statements by the FDA prior to 2018 raising concerns about the use of GCFID testing?
A. Not that I recall.
Q. Do NDMA's properties make it hard to detect with standard laboratory testing?
MR. SLATER: Objection. You can answer.
A. Could you repeat the question?
MS. MILLER: Go ahead, David.
(Record read.)
A. How do you define "standard laboratory

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testing"? GCMS was available, was in use. And it's detectable.
Q. Did the FDA ever state that NDMA's properties make it hard to find, to detect, in standard laboratory testing?
A. I believe we just covered that.
Q. No, we didn't. This is a different question.
A. Can you repeat the question, then?
Q. Did the FDA ever state that NDMA's properties make it hard to detect in standard laboratory testing?
MR. SLATER: I'm sorry, could you read that question back? It went so fast, I couldn't honestly hear it. If somebody could read it back, please. It sounded like the same question so I must be missing something. It's different.
(Record read.)
MR. SLATER: Objection. I thought this was answered already. You can answer again.
A. I don't recall if they made that statement to, that includes the words "standard laboratory testing."
Q. If the FDA stated in January 2019 that NDMA's properties make it hard to detect in standard

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laboratory testing, would you disagree with that statement?
A. Yes.
MR. SLATER: You can answer.
Q. Do you know whether any organic chemists at the FDA reviewed ZHP's Drug Master Files?
A. I don't know who reviewed their files.
Q. Are Drug Master Files reviewed in connection with ANDAs?
A. Yes, to my knowledge.
Q. And who reviews them?
A. My understanding, the FDA reviewers.
Q. And do you know whether the people who review DMFs, and this time I mean Drug Master Files, in connection with ANDAs are organic chemists?
A. I don't know what their positions are.
Q. Do you believe that you are more qualified to address the potential for DMF degradation than organic chemists of the FDA?
MR. SLATER: Objection.
You can answer.
A. I'm relying on the expert testimony of Drs. Hecht and Najafi.
Q. Do you agree with the FDA that it generally needs to be recognized that there's a risk

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of an impurity occurring as a result of a manufacturing process, to know the impurity should be tested for?
MR. SLATER: Objection, you can answer.
THE WITNESS: I'm so sorry, can I please have that read back?
MS. MILLER: Yes. David, did you get it or to you want me to do it?
(Record read.)
MS. MILLER: Thanks, David.
A. Yes.
Q. Do you agree with the FDA that in order to implement a risk assessment for any genotoxic impurity, there must be recognition that can occur in a product's manufacturing?
MR. SLATER: Objection. You can answer.
THE WITNESS: I'm so sorry, can you repeat again?
(Record read.)
MR. SLATER: Objection, you can answer.
A. It's incumbent upon the firm to do the research to identify the potentiality for that impurity to occur.
Q. Are you saying you disagree with the FDA on this as well?

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A. I do. I do disagree, if I'm understanding correctly.
Q. You disagree with the FDA that the risk to patients based on the maximum possible exposure appears to be small?
MR. SLATER: Objection. Same objection as before. You can answer again.
A. I -- I have no way of knowing.
Q. When you were at the FDA, were you responsible for evaluating CGMPs compliance?
A. Yes.
Q. How did you do that?
A. Auditing the firms.
Q. And what did those audits involve?
A. Reviewing their documentation, their SOPs or constructions, anything related to the manufacture of the product -- um -- a visit to the firm usually to confirm that they were actually following their procedures.
Q. In the year-and-a-half at the FDA, you did not evaluate CGMP compliance by any API manufacturer for human drugs, correct?
A. It was more than a year-and-a-half. But no, I did not do any inspections of API manufacturers.

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Q. And when you say it was more than a year-and-a-half, you mean it was a year and nine months?
A. Yes.
Q. In your year and nine months at the FDA, did you ever evaluate CGMP compliance by manufacturers of finished drug products for humans?
A. No.
Q. Do you teach any courses on API manufacturing?
MR. SLATER: Objection.
You can answer.
A. I do not teach anything related to the actual manufacturing process of APIs.
Q. Can you tell me what courses you've taught for the last two years?
A. I've taught drug and biologics quality, I've taught medical device quality, medical device regulations, quality systems in medical products, I've taught a validations course, I've taught an emerging technologies course; um -- I co-instructed on a auditing course.
Let me say on the validation course, that is also a co-instruction. And I believe that's -- that's -- I believe that's a complete list.

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Q. What do you teach in your drug and biologics quality course?
A. We teach the regulations that are -- that they are required to meet in manufacturing at a broad level. We teach about auditing and the kinds of audits that they might receive. I'm thinking about the curriculum here for a minute.
We teach about CAPAs and deviations, non-conformances -- CAPA, C-A-P-A, Corrective and Preventive Actions. So broadly -- broadly, those are -- those are major topics we're covering.
Q. What is a CAPA?
A. Corrective And Preventive Action.
Q. What does that require?
A. When a firm receives information from an audit that they need to make a correction, there are several instances that a CAPA can be opened. That's one of them. We can open a CAPA if we are finding repeat issues with the process. A CAPA might be opened if there's a problem with the test method. A CAPA can be opened if -- with a customer complaint.
So there's -- there's many times which CAPAs can be opened.
Q. What's the relationship between CAPAs and warning letters?

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A. So if FDA issues a warning letter, firms usually will open a CAPA to address the issue cited in the warning letter.
Q. In your opinion, would any failure by an API manufacturer to detect an unknown genotoxic impurity constitute a CGMP violation?
A. Yes.
Q. Is there ever a circumstance where an API manufacturer would fail to detect an unknown impurity that would not be a CGMP violation?
MR. SLATER: Objection, you can answer.
A. Not to my knowledge.
Q. Are pharmaceutical manufacturers required to test for every possible impurity?
MR. SLATER: Objection, you can answer.
A. They are required to test for every impurity that becomes suspected or known as a result of their risk analysis.
Q. And where is that requirement set forth?
A. To open a CAPA or to do an investigation?
Q. I think we were talking about impurities, right?
A. We were.
MS. MILLER: Can you repeat the

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question?
(Record read.)
MS. MILLER: She mentioned a requirement and I'm asking, where is the requirement set forth fully?
THE WITNESS: Can we refresh a bit back, because I don't remember which requirement we're talking about.
Q. We were talking about the requirement to --
MR. SLATER: She asked for the prior testimony to be read back so she'd have a context for that last question. So can --
MS. MILLER: I was telling --
MR. SLATER: David, could you read back, please, the prior question and answer before the last question?
MS. MILLER: Adam, could you try not to interrupt? Thanks.
MR. SLATER: I'm not interrupting. I'm asking him to do what she asked to do. And you're not going to bull -- hang on, David -- you're not going to bulldoze over me, Jessica. I'm not going to be bulldozed. If the witness asks to have the testimony read back, you're not allowed to block her

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from hearing it in order to answer the question.
So she asked to have the prior testimony back, so I'm asking our court reporter to read back the prior question and answer, then the question just asked, so she can hear what she asked to hear.
(Record read.)
Q. All right, go ahead and answer.
A. So in ICH Q9, there is verbiage requiring a risk assessment be done. In ICH M7, you -- the document has verbiage that states the company has to assess the mutagenic or carcinogenic impurities it might find. There are other guidance documents that are also speaking to the same requirement.
Q. Do you agree that if a pharmaceutical manufacturer has no knowledge that a potential impurity may form, it is not required to test for that impurity?
A. No, I do not.
Q. Are all pharmaceutical companies presently required to test their drug substances for NDMA and NDEA?
MR. SLATER: Objection.
You can answer.
A. Only if they have done a risk assessment

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and suspect NDMA or NDEA can be formed.
Q. If a manufacturer does a risk assessment and does not suspect an NDMA or NDEA could be formed, is it required to test for those impurities?
MR. SLATER: Objection, you can answer.
A. If they perform a risk assessment and they don't have a reason to suspect NDMA or NDEA could be formed, then they wouldn't need to test for it. However, if they did a risk assessment and it was a poor risk assessment and they missed the fact that NDMA or NDEA could be formed, then that's incumbent upon the firm, they need to -- and would be expected to have done that analysis.
Q. Are you qualified to determine whether an API risk assessment was adequate or not?
A. When we went out to do inspections, and if it involved a laboratory method or procedure, then an expert from headquarters would accompany the investigator on the audit and make that assessment.
Q. That doesn't really answer my question, which is simply, do you believe that you are qualified to determine whether an API manufacturer's risk assessment is adequate or not?
MR. SLATER: Objection.
You can answer.

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A. For NDMA? If their risk assessment was adequate for NDMA?
Q. Just generally. Do you have the expertise to review a risk assessment for API and determine whether or not it was adequate?
MR. SLATER: Objection.
You can answer.
A. My expertise is not in the area of API. Yes, I can -- I assess risk assessments for medical devices but again, I did not inspect and I was not trained on APIs.
Q. What expertise is required to determine whether a manufacturer's risk assessment or a change in an API process is adequate?
A. Are you asking from FDA's perspective?
Q. I'm asking from your perspective. What expertise would be required to determine whether a manufacturer's risk assessment for a change in a manufacturing process was adequate?
A. Anyone that's reviewing and approving that risk assessment should have education and experience in that area and be qualified to make that assessment and sign off on that document.
Q. So that would be a chemist, for example?
MR. SLATER: Objection.

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You can answer.
A. In the case of an API, in this specific instance, I would expect it would be someone with chemistry background.
Q. So that's not you; right?
A. That is right.
MR. SLATER: You can answer.
A. Yes, that's right.
Q. Did Novartis find NDMA in Valsartan API?
A. Yes, using a third-party laboratory.
Q. Did Novartis do its own testing?
A. They did.
Q. And did that own testing find NDMA?
A. Yes.
Q. So Novartis both did its own testing and had a third-party test?
A. That's my understanding.
Q. If Novartis found NDMA, why did it go to a third party?
A. My recollection is, they went, they had the unknown peaks and they went to a third party lab and then subsequently, they tested themselves.
Q. You're saying they tested after they went to the third-party lab, not before?
A. I don't remember that Novartis

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identified NDMA specifically. They were asking for ZHP to identify the unknown peaks. And they went to a third-party lab and the third-party lab identified the peak as NDMA.
Q. Is it your opinion that the use of GCFID to test Valsartan API was a CGMP violation?
MR. SLATER: Objection.
You can answer.
A. Unto itself, not a GMP violation. Are you asking if they --
MR. SLATER: Why don't you wait for the next question.
Q. You can go ahead. What were you saying?
A. I'm good. I'm done.
Q. If ZHP had used GCMS to test Valsartan API but did not identify the NDMA using that method because other expected impurities peaked at the same time on the chromatogram, would that have violated CGMP?
A. Yes.
MR. SLATER: Lack of foundation. You can answer.
You've got to let me object. You've got to pause.
A. Yes, that's a violation.

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Q. And why do you say that?
A. Because any peaks that are found need to be identified.
Q. Do you know if ZHP ever used GCMS to test Valsartan prior to the recall?
A. It's my understanding from Dr. Li's testimony that they had used GCMS.
Q. And do you know why that GCMS did not reveal the presence of NDMA?
MR. SLATER: Objection.
You can answer.
A. I don't know that it didn't reveal NDMA, but I don't know the ZHP would not have identified and then immediately gone to the FDA and notified.
Q. Do you know whether Novartis used GCFID or GCMS to test Valsartan as of April 2018?
A. I don't know.
Q. If Novartis used GCFID to test Valsartan as of April 2018, was Novartis in CGMP violations?
A. They are not the manufacturers of the API. So I don't know exactly what you're asking.
Q. If the manufacturer of the finished dose product used GCFID instead of GCMS, was that manufacturer of the finished dose product in violation of CGMPs?

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MR. SLATER: Objection. Foundation.
You can answer.
A. That issue is the API, and they -- Novartis is not aware of the processing that the API manufacturer would have used in the manufacture of the API.
Q. Have you ever tested a product using GCFID or GCMS?
A. No, I have not.
Q. Do you know whether GCFID or GCMS was the industry standard for evaluating pharmaceutical impurities in 2013?
A. It was available in 2013. Whether or not the words "industry standard" could be used, I can't answer. But it was certainly available.
Q. I think maybe I didn't ask my question clearly. But do you know whether --
MS. MILLER: -- I'm sorry. Can we just go off the record?
VIDEOGRAPHER: The time is 10:26. This ends media unit number 3. We're going off the record.
(Discussion off the record.)
(Recess taken.)
VIDEOGRAPHER: The time is 10:43. This

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begins media unit number 4. We're back on the record.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. I wanted to ask you what the basis is for your opinions with respect to GCMS and GCFID. Is that relying on Hecht and Najafi reports or do you have any other basis for those opinions?
A. Primarily Hecht and Najafi's reports. But, I've, you know, read some of the literature as well.
Q. When you say you read some of the literature, what do you mean?
A. That was cited in my report.
Q. Literature cited in your report about GCFID versus GCMS?
A. No, I don't believe I spoke about -- we could go to the report but specifically about GCMS versus GCFID.
Q. My understanding from your testimony, maybe I misunderstood, is that you're offering an opinion that the use of GCFID testing by ZHP was improper, correct?
MR. SLATER: Objection.
You can answer.

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A. My opinion is that GCMS was available and at the time they were doing this work, they should have used GCMS.
Q. Correct. And so I'm asking, do you have any basis for that point other than the opinions of two other experts?
A. And the literature that says that that technology was available.
Q. What literature are you relying on with respect to GCMS and GCFID, that's what I'm trying to get at?
A. I need to go back to my report --
Q. Okay.
A. -- and see.
MR. SLATER: You're allowed to access the report itself. If you don't need someone else to put it up, it's better if you just access it yourself.
MS. MILLER: I believe we introduced the report as Exhibit 1.
MR. SLATER: But she can use her own copy of it.
MS. MILLER: I wasn't suggesting that, I was just saying that's introduced here as Exhibit 1.
Q. Where would I look in your report to see

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what literature you relied on with respect to GCFID versus GCMS testing?
MR. SLATER: Objection.
You can answer.
A. It's going to take me a bit to go through.
(A pause in the proceedings.)
A. Are you asking for verbiage that compares the two methods?
Q. I'm asking whether there are any materials you're relying on for your opinions regarding GCFID and GCMS besides these two expert reports.
MR. SLATER: Objection. The question is very, very vague and overbroad.
A. I agree. I really would feed you to be more specific.
Q. Okay. Adam is objecting for the record, but you still need to answer my question.
Are you relying on any literature or any other documents besides the two expert reports that you have cited for your opinions regarding GCMS and GCFID?
MR. SLATER: Objection, again. The witness just told you the question is unclear to her.

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So -- it's okay, you don't have to rephrase it, but I think she's allowed to say "I can't answer the question, I don't understand it," which is what she just --
MS. MILLER: Don't coach the witness. I did rephrase it.
MR. SLATER: I'm not coaching the witness. What you did is, you bulldozed over her request as to what you're asking, and asked the same question again.
A. I am still unable to answer that question.
Q. You're unable to let me know whether you cited any literature to support your opinions on GCFID or GCMS besides the two expert reports?
MR. SLATER: Objection.
You can answer. Same objection.
A. Now you seem to have rephrased it, and you put "or" in there. Did I -- it's -- are you asking for a specific citation in my report?
Q. Can you cite any literature anywhere in your report that relates to either GCFID testing or GCMS testing? Let's start there.
(A pause in the proceedings.)
A. GCFID testing is only referenced, that I

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find, in expert witness testimony.
Q. You testified earlier that your opinions about GCFID testing and GCMS testing are based both on expert reports, and on literature.
I'm just trying to identify what that literature is that you were referring to.
MR. SLATER: Objection. Continued objection. Argumentative.
A. Now, I just can't answer that. I'm sorry.
Q. You cannot answer whether you cite any literature related to GCFID or GCMS testing in your report?
MR. SLATER: Objection.
Argumentative --
A. I did not cite any literature on GCFID. I will look now to see if I cited it for GCMS.
(A pause in the proceedings.)
Q. If you're going to be reading your report for more than a few minutes, the form in this litigation is, we go off the record, so let me know.
A. I do not see any literature citings in my report other than citing to Dr. Hecht and Dr. Najafi's reports.
Q. When you said earlier that you were

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relying on their reports and literature for your testing opinions, do you know what literature you were referring to when you made that at that moment?
MR. SLATER: Objection. One second, Dr. Bain. Objection. Lack of foundation.
You can answer. And also to the form of the question.
You can answer.
A. I would have to go back to each of their reports. I do not remember at this moment the names of the literature that was cited in their reports.
Q. So to the extent you say you're relying on literature, it would just be literature cited by other experts?
MR. SLATER: Objection, you can answer.
A. Yes. It would have also been literature I reviewed after seeing it in their reports.
Q. Are you aware of any scientific literature stating that DMF can degrade into diethylamine in conditions present in ZHP's manufacturing process?
MR. SLATER: Objection.
You can answer.
A. Literature on the degradation?
Q. Can you point to any literature stating

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that DMF can degrade into diethylamine in the same conditions that are present in ZHP's manufacturing process for Valsartan?
A. In the 1978 IARC monograph.
Q. Does the 1978 IARC monograph say that DMF can degrade into diethylamine in the same conditions that are present in ZHP's manufacturing process?
A. To the best of my recollection, yes. I would need to go back and read the exact verbiage. But it does discuss the degradation.
Q. Do you know what the boiling point is for DMF?
A. No, I don't.
Q. Do you know what the highest temperature was that occurred for DMF in the zinc chloride manufacturing process for Valsartan?
A. No. I don't.
Q. Had you heard of Tetrahedron Letters before becoming part of this litigation?
A. No, I had not.
Q. What is Tetrahedron Letters?
A. It was an article which, again, if I could pull it up I could tell you the title, that discussed the formation of the nitrosamines.

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Q. But what is Tetrahedron Letters?
A. I don't know specifically.
Q. And it's your recollection that the IARC monograph addresses DMF degrading into diethylamine?
A. Yes.
Q. Can we go back to the supplemental reliance list which is Exhibit 2.
Take a look at the scientific materials. You added two scientific materials here. Do you recall why you added these to your supplemental reliance list? The Juillard article, I don't know how to pronounce it, and the Long article?
A. I would have to go back and look at the articles themselves to see exactly what I pulled out from that article that is pertinent to my opinion.
Q. When did you read these two articles?
A. Within the last few weeks.
Q. And how did you come to learn of them?
A. From counsel.
Q. You didn't perform the literature search that identified these two articles?
A. No, I did not.
Q. They were e-mailed to you by counsel?
A. Yes.
Q. Do you know who Long and Meek are?

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A. No.
Q. Do you know where they work?
A. No, I don't.
Q. Do you know what WHO stands for in the second article?
A. World Health Organization.
Q. Did you rely on this article?
A. Yes.
Q. What did you rely on this article for?
A. If we could pull the article up, then I could -- I could see.
Q. You did not read the article before you wrote your report?
A. No.
Q. Okay. Let's pull up the Long article. We're going to mark the Long article as Exhibit 4.
EXH (Susan Bain Exhibit 4, article draft by Long, Meek, et al, "N,N-DIMETHYLFORMAMIDE", marked for identification, as of this date.)
Q. If you could turn to page 6. WHO is the World Health Organization, correct?
A. Yes.
Q. And what do you know about the World Health Organization?
A. Can you be a little more specific?

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Q. Is it a reputable body?
A. I'm not sure I could assess that. They are a very, very large organization, as I understand it. And I couldn't comment on all of their interactions.
Q. Did you include this article on your reliance list because you thought it was a reputable article?
A. Yes.
Q. And what made you think that?
A. I found their article to be scientific and reasonable as far as I could assess. Yes, World Health Organization generally has a good reputation, but again, I can't speak for everything they do all over the world.
Q. Do you know which of your opinions does this article support?
A. Again, I'd have to go back through the article, and see.
MS. MILLER: All right, let's go off the record, look at the article for two minutes, and -- David, I know I said 2 o'clock. Lunch will probably be more like 2:15 because I want to finish questioning on this article.
So if we could go off the record while

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you are you review this article, and if you could let me know, which --
THE WITNESS: I need to be able to scroll.
VIDEOGRAPHER: The time is 11:03, we're going off the record.
(Discussion off the record.)
VIDEOGRAPHER: The time is 11:05, we're back on the record.
Q. Are you able to tell me without spending half an hour reading this 60-page article, why you cited it in your reliance list?
A. I would need some time to read through this article.
Q. Your supplemental reliance list was submitted on Sunday, right?
MR. SLATER: This is getting to be argumentative. Let's just ask questions, please.
MS. MILLER: That is my question.
Q. Was your supplemental reliance list submitted on Sunday?
A. That's -- yes.
Q. Do you recall why you included this article in that supplemental reliance list?
A. I do not remember off the top of my

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head, no, without reviewing it.
Q. Can we turn to page 6. Can you read the sentence that begins "Temperatures"?
A. What I'm looking at. I need to -- I'm sorry, could I read what?
Q. The sentence that begins with the word "Temperatures."
A. On page 6? "Temperatures in excess of 350 degrees C are required for dimethylamine."
Q. What happened? You stopped mid sentence.
A. I'm sorry. Temperatures -- "Temperatures in excess of 350 degrees C are required for DMF to decompose into carbon monoxide and dimethylamine."
Q. Do you have any reason to doubt the statement?
A. No.
Q. Do you know what the highest temperature was in ZHP's manufacturing process?
A. I do not.
Q. Do you know if it reached 350 degrees Celsius?
MR. SLATER: Objection. You can answer.
A. I don't recollect without looking.

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Q. Did you cite this article in your reliance list because it addresses the decomposition of DMF?
A. Again, I need to read a little before and after to get some more context.
Q. I'm just asking if you cited it in your expert report because of this statement.
A. Not just because of this statement, no.
Q. Was this one of the statements for which you were citing this article in your supplemental report -- in your supplemental reliance list, I apologize?
A. Not specifically, from my recollection.
Q. Do you recall reading this sentence?
A. Yes.
Q. Does it support your opinions?
A. My opinion doesn't change as a result of this sentence.
Q. Does the sentence support your opinion about what was known in the scientific community in 2011 to 2013 about the circumstances required for the degradation of DMF?
A. Can you repeat that?
MS. MILLER: David, go ahead.
(Record read.)

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A. It doesn't directly support my opinion because in, I believe it was Dr. Hecht's report, he addressed the temperatures and how the longevity of the actual process could affect the formation of the NDMA.
Q. So are you saying that this article is contrary to what Dr. Hecht said in his report?
MR. SLATER: Objection.
You can answer.
A. Not necessarily, no.
Q. In what ways is it not contrary to what he said?
A. The article says that temperatures in excess of 350 degrees C are required. However, Dr. Hecht's testimony was that the length of time of the reaction or of the process could also affect the formation of NDMA.
(Continued on following page.)

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Q. Did Dr. Hecht write in his report that temperatures in excess of 350 degrees are required for DMF to decompose into dimethylamine?
MR. SLATER: Objection. You can answer.
A. I would have to go to his report to see if that exact verbiage is that.
MS. MILLER: Okay. Let's go off the record. Poor David is hungry.
VIDEOGRAPHER: The time is 11:11. We're going off the record.
(Discussion off the record.)
(Luncheon recess: 11:11 a.m.)

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AFTERNOON SESSION
(11:55 a.m.)
SUSAN BAIN, having been previously sworn, resumed the stand and testified further as follows:
VIDEOGRAPHER: The time is 11:55. We're back on the record.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. Are you offering any opinions in this litigation with respect to Teva or Torrent?
A. No, I'm not.
Q. When did you first form the opinion that ZHP had violated CGMPs?
A. After reviewing the information that was provided to me by counsel.
Q. Did you agree to serve as an expert before you reached that conclusion or after?
A. Before.
Q. Does CGMPs evolve as technology and scientific or medical knowledge is gained?
A. I'm sorry, I didn't get the last word of what you said.
Q. Did CGMPs evolve along with technological and scientific developments?

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MR. SLATER: Objection.
You can answer.
A. Are you asking if CGMPs are modified?
Q. Do CGMPs change as technology and science evolve?
MR. SLATER: Same objection.
A. In my experience, not to a great extent. The C in front of GMP is there because it's current.
Q. Is it your opinion that ZHP committed the same CGMP violations with respect to the zinc chloride process as it did with respect to the quenching, TA with quenching process?
A. Yes.
Q. And why is that?
A. Because in both cases, it was a failure for identify the peaks, unknown peaks.
Q. If a manufacturer tries to identify unknown peaks and fails, is that a CGMP violation?
MR. SLATER: Objection.
You can answer.
A. Incumbent upon the manufacturer to identify the unknown peaks because, just as in this case, they could be genotoxic.
Q. So if a manufacturer attempts to identify unknown peaks and fails, is that a CGMP

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violation?
MR. SLATER: Objection.
You can answer.
A. If they introduce the product into interstate commerce, it is.
Q. You wrote in your report that ZHP violated CGMPs because it failed to comply with 210(a) and 211(b), do you recall that?
A. Yes.
Q. Did 210(a) and 211(b) apply to API manufacturers?
A. Yes.
Q. This actually said that 21 C.F.R. Parts 210 and 211 apply to API?
A. I'd have to go back and look at the preamble. But ICH Q7 tells us that APIs have to be manufactured under CGMPs.
Q. Is ICH Q7 binding or advisory?
A. It's not legally binding; however, it is the guidance that FDA expects you to follow and if you're not following it, you must be prepared to explain to FDA in writing why you're not following the guidance document.
Q. Is there a guidance document produced by the FDA that says if you suspect sodium nitrite is

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part of your drug manufacturing process, then you have to test for nitrosamines?
A. There's an ICH guidance document that talks about impurities in your drug substances. There's also an ICH guidance document that talks about assessing impurities.
Q. If a manufacturer suspects that sodium nitrite is part of a drug manufacturing possess, is it obligated to test that product for nitrosamines?
MR. SLATER: Objection. You can answer. Incomplete hypothetical.
A. The firm is required to do a risk assessment and determine if there's a potential for any impurities to be formed and, if there are, to pursue identification.
Q. Did they do a risk assessment?
MR. SLATER: I lost the first part of the sentence.
MS. MILLER: Did ZHP do a risk assessment.
A. Yes.
Q. Do you know how many pharmaceutical products there are that use sodium nitrite?
A. No, I do not.
Q. Do you know whether there were other

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pharmaceutical products that use sodium nitrite at the time that ZHP was using the zinc chloride process?
A. No, I don't.
Q. If none of those manufacturers tested for nitrosamines, were they all in violation of CGMPs?
MR. SLATER: Objection, lack of foundation, incomplete hypothetical.
You can answer.
A. It would depend on their manufacturing process.
Q. Do you know how many pharmaceuticals have a manufacturing process that involves a nitrite and a secondary amine?
A. I do not.
Q. If a pharmaceutical company has a manufacturing process that involves a nitrite and a secondary amine, is that manufacturer required to use CGMS testing to test for nitrosamines?
A. The firm is required to do a risk assessment and, if the risk assessment shows that there's a chance for the impurities to form, then they are obligated to go through and identify the impurity.

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Q. Is it your position that any violation or failure to comply with an ICH provision is a CGMP violation?
A. Yes.
Q. So even though ICH guidelines are not binding, if you don't follow an ICH guideline, it's your opinion that there is a CGMP violation?
MR. SLATER: Objection.
You can answer.
A. Yes.
Q. And what's that based on?
A. I'm sorry?
Q. What's that opinion based on?
A. FDA recognizes ICH guidance documents and has adopted them. And they are used in the assessment of compliance.
Q. Is there a statement somewhere by FDA that if you don't comply with an ICH provision you're engaged in a CGMP violation?
MR. SLATER: Objection.
You can answer.
(A pause in the proceedings.)
MR. SLATER: Objection, you can answer.
A. I'm sorry. I'm sorry, I would have to go to the specific verbiage on FDA's website where

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they talk about use of ICH guidance documents under FDA's pursue.
Q. Do you teach courses on CGMP?
A. I teach courses on quality --
Q. Just, do you teach your students that, according to the FDA, if you don't follow guidance, it's a CGMP violation?
MR. SLATER: Objection. You could answer. Foundation.
A. If you don't follow a guidance document, you must be prepared to explain to the FDA why you're not following that guidance document. That -- that practice needs to be in writing and if it's applicable, it has to be validated.
Q. And where does FDA say that?
A. Again, I would have to look that up. But there is verbiage that talks about enforcement of guidance documents.
Q. Does the FDA talk about enforcement of guidance documents even though they are only guidance?
A. Yes.
Q. Does the FDA use the word "enforcement" with respect to guidance documents?
A. Again, I would have to go to the FDA

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website and check if the word "enforcement" specifically is used.
Q. Okay. I thought you were testifying that the FDA uses the word "enforcement" with respect to guidance documents. I may have misunderstood.
A. They do -- again, guidance documents are considered by the FDA as the most current thinking on the agency's part. And you must follow those guidance documents unless you have a reason and can justify why you are not following them, and that justification must be in writing.
Q. But you don't know where that requirement is set forth.
A. Not right off the top of my head.
Q. Do you agree with the statement that guidance documents do not establish legally enforceable rights or responsibilities?
MR. SLATER: Objection.
Q. Go ahead.
A. That is -- yes, I agree with that verbiage.
Q. You do agree that guidance documents do not establish legally enforceable rights or responsibilities?
MR. SLATER: Objection.

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You can answer.
A. I was saying that the FDA, that, again, you must follow the guidance documents unless you're unable, and if for some reason you are unable, then it must be documented and if that's not done, you will be cited on a FDA form 483.
Q. So are you saying you disagree with the statement that guidance documents do not establish legally enforceable rights or responsibilities?
MR. SLATER: Objection.
You can answer.
A. With the exception that I told you. If you can't follow it, that you've justified and presented that.
Q. As a general matter, do you know that guidance documents establish legally enforceable rights or responsibilities?
A. Yes.
Q. So as a general matter, do you disagree with the statement, "Guidance documents do not establish legally enforceable rights or responsibilities"?
MR. SLATER: Objection.
You can answer.
A. I'm thinking about the double negative.

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Can you read back?
Q. As a general matter, do you disagree with the statement, "Guidance documents do not establish legally enforceable rights or responsibilities"?
A. I disagree.
Q. Okay. Let's turn to page 29 of your report.
A. Got it.
Q. Are we there?
A. Yes.
Q. Okay. Do you see where it says here at the bottom that, "Mr. Gu was also asked about the finding by the" --
A. Yes.
Q. -- "European Medicines Agency that, contrary to what the company stated in their retrospective analysis of the process change, the core principles of ICH Q8, Q9, and Q10 were not considered, and potential impurity profiles and associated risks were not addressed by the R&D laboratory"? Do you see that language?
A. Yes, I do.
Q. And you see that when asked if he agreed with that finding, Mr. Gu said yes?

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A. Yes.
MR. SLATER: It says more than that, just for the record. The sentence doesn't stop with "yes."
Q. Turn to Mr. Gu's testimony.
MS. MILLER: I'm going to introduce his deposition as Exhibit 5.
EXH (Susan Bain Exhibit 5, transcript of deposition of Eric Gu, Ph.D., held 4/5/21, marked for identification, as of this date.)
MS. MILLER: Sorry, we have a technical problem. Alex is putting up the 4/5/21 Gu deposition which we're going to mark as Exhibit 5.
(A pause in the proceedings.)
MS. MILLER: Are we there, Alex?
MR. PERRY: Yes.
Q. Can we turn to page 245. I wanted to read to you from page 245, line 13 -- well, let's go to 74, 16 to 75, 4. That's what I wanted.
MR. SLATER: Which page did you say? Could someone please tell me which page we're going to? I did not hear.
MS. MILLER: It's right up on the screen, Adam. It's page 73 to 76. If you just look on the screen it shows you the page numbers.

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MR. SLATER: Well, could you tell me what page and lines you are actually focused on, as opposed to the four pages that only two of them are actually visible? I don't know why it's so hard to say, "I'm going to this page and line." I don't understand. It's just to be polite, please.
MS. MILLER: Adam, you haven't even given me a minute. I was going to ask the witness to read a page and line. Just have a little patience.
Q. Can you please read 74 line 16, 'till 75, line 4, out loud.
A. I can't see 75.
Q. Well, you'll see it when he -- he made it bigger to make it easier for you to read. Why don't we start with a question. "Question." Go ahead.
A. What line would you want to start at?
Q. Sixteen.
A. Sixteen.
"Question: I'll ask it differently. When Syncores was helping to develop the zinc chloride process, did it identify NDMA as a potential impurity that had to be tested for?
"Answer: As I said, okay, at 2011, we did the process development based on the ICH

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guidelines. And at that time, okay, we followed the GMP protocols, and we didn't know the NDMA was the potential impurity in the process, and the industry didn't know. The FDA doesn't know. And nobody knows at that time."
Q. Did you quote that in your report, that entire section?
A. What was the question?
Q. Did you quote any of that in your report?
A. Can you scroll to 74 again, please? I'd have to go through Mr. Gu's entire testimony.
Q. You can't tell us today whether you quoted any of that in your report?
A. I don't know whether I quoted any of those exact sections.
Q. And if we could turn to 169, 24 to 170, 10. 169, 24. And could you read 169, 24, to 170, line 10. Question and then answer.
A. (Reading):
"Question: Then I guess we'll come back to where I originally was. I'm asking about ZHP and what ZHP did.
"Answer: ZHP did whatever possible to improve the process to make sure that we make better

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or equal quality product, to follow all the ICH guidelines, to follow the CGMP guidelines, to gain approval from the FDA and EDQM for the Valsartan product. That's for this case. That's what's been done."
Q. Do you recall if you quoted that in your report?
A. I do not believe I quoted that in my report. Again, I would have to look specifically.
Q. How did you select which parts of Dr. Gu's testimony you included in your report?
A. I selected sections that I felt were germane to GMP compliance and specifically where he noted, it was noted, I guess by the EMA that they were discussing that ZHP had followed ICH Q8, 9 and 10. And they were -- I'm sorry, that they were not considered.
Q. Was it relevant to your opinion that Dr. Gu believed that ZHP did whatever possible to improve the possess to make sure that they made a better or equal quality, to follow all ICH guidelines and to follow the CGMP guidelines, was that relevant to your report?
A. I took it into consideration. However, the company stated that they didn't consider ICH Q8,

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9 and 10, and the potential impurity profiles and associated risks. That's important.
Q. If you considered the two passages that we just read together in assessing your opinions and in writing your report, is there a reason why you didn't include them in your summary of Dr. Gu's deposition?
A. I included what I felt showed that they were in violation to CGMP.
Q. Did you try to be balanced and include also testimony that suggested that ZHP was trying to comply with CGMP and ICH guidelines?
A. I took it into consideration. However, what I was most interested in was the fact that they did not follow ICH Q8, 9 and 10.
Q. Why were you more interested in that than in their testimony that they attempted, did whatever possible to make sure that they followed all ICH guidelines?
A. Because it leads to the violation against GMPs.
Q. Are a company's efforts to comply with ICH guidelines and CGMP guidelines relevant?
A. Yes.
Q. When you represent companies, do you

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consider their efforts to follow ICH guidelines and CGMP guidelines to be relevant?
A. Yes.
Q. Were ZHP's efforts to follow CGMP guidelines and follow all the ICH guidelines as set forth in Dr. Gu's deposition testimony relevant to your opinions in this case?
A. I'm sorry, relevant to?
Q. Your opinions in this case.
A. I'm sorry, could you read that question back again?
Q. Sure. David will do it.
(Record read.)
A. I took them under consideration. But I looked as a whole.
Q. Would I be able to find discussion of the testimony that we just went over in your report?
A. I don't believe I addressed this particular section in my report, but again, I would have to look to make sure.
Q. Are you surprised to hear that I could not find a discussion of either of these passages in the deposition, in your report?
A. No.
Q. Why not?

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A. Because my report focused only CGMP violations.
Q. Are efforts to follow the CGMP guidelines relevant to an analysis of a particular company's efforts with regard to CGMP regulations?
MR. SLATER: Objection. That was already asked and answered.
You can answer again.
A. Can you tell me the question again?
(Record read.)
(A pause in the proceedings.)
Q. Are you answering?
A. Sorry, was there a question?
Q. Yes. David repeated the question.
MR. SLATER: Do you want to have it asked again?
THE WITNESS: I do want to have it asked again. I'm sorry, I didn't know that I was being asked -- go ahead.
(Record read.)
MR. SLATER: Objection, asked and answered.
You can answer again.
A. So, you can consider their efforts, but it doesn't negate the requirement to meet and follow

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the CGMP requirements.
Q. ICH 8 covers what information should be included in an NDA or an ANDA, right?
MR. SLATER: Which one did you say, Q-what?
MS. MILLER: Eight.
MR. SLATER: Eight? Can we pull that up --
THE WITNESS: Yes, please.
Q. Do you know, without looking at the ICH Q8 document, what it covers?
A. Generally, but not specifically. But I don't know whether it specifically tells someone exactly what needs to be in a DMF.
Q. What does ICH Q8 generally cover?
A. Pharmaceutical development.
Q. Does ICH Q8 apply to API product development?
MR. SLATER: To what?
Q. Does ICH Q8 apply to API development?
A. It more broadly discusses product development but ICH Q7 specifically dresses the GMPs or APIs.
Q. I said Q8, right?
A. Yes.

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Q. You have something in your report about ICH Q8, and ZHP allegedly not complying with ICH Q8. So I'm trying to understand, does ICH Q8 apply to development of APIs?
A. Yes.
Q. It's your understanding that ICH Q8 applies to API?
A. Yes.
Q. And what is that based on?
A. My background and training.
Q. And is it your opinion that ICH Q9 creates any expectations beyond regulatory requirements?
MR. SLATER: Objection.
You can answer.
A. It's my understanding it does not have any requirements beyond regulatory requirements.
Q. So what's the purpose OF ICH Q9?
MR. SLATER: Objection to form.
A. Risk assessment.
Q. Does ICH Q9 say that the rules of informal risk management process such as empirical tools and/or procedures can be considered acceptable?
A. I would have to pull the guideline and look specifically.

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MR. SLATER: You're allowed to pull the guideline right now while you're being asked about it.
Q. Do you consider yourself to be a CGMP expert?
A. Yes.
Q. As a CGMP expert, do you know whether ICH Q9 addresses formal risk assessments versus informal risk assessments?
A. I would, again, have to go back to Q9 and read it specifically.
MR. SLATER: And by the way, objection to the terminology, and lack of foundation.
Q. What does ICH Q9 address?
A. Quality systems.
Q. Do you have any opinions regarding ZHP's quality systems?
A. I believe they established a quality system but it was deficient in some cases, especially in areas of complying with some of their internal SMPs.
Q. Are you offering an opinion that ICH Q8 was not followed by ZHP?
A. Yes.
Q. And what is your basis for that opinion?

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A. Again I go back to the warning letter. The issues that were cited were not considering the impurities, the complaints that were not investigated, the fact that it is -- quality is ZHP's responsibility.
Q. Other than the warning letter, do you have any other basis for your opinion that ZHP did not comply with Q8?
A. Only Q8?
Q. And Q3. We'll get to the rest later.
A. But again, I would like to pull up Q8 and --
Q. I understand. I'm asking what your opinions are in this litigation.
A. I understand. But I need to read Q8 to make sure I understand the parameters.
Q. So you're unable without reading Q8 to tell me the basis for your opinion that ZHP violated ICH Q8?
MR. SLATER: Objection, counselor. It's very argumentative and there's a serious foundational issues to these questions, ignoring her report. But you can go ahead.
A. Again, if you'd permit me time to pull up Q8, I could better answer your question.

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Q. What is your basis for your opinion that ZHP violated ICH Q10?
A. ICH -- I'm sorry, ZHP was required, again, to identify the peaks, the unknown peaks.
Q. Did ZHP attempt to identify unknown peaks?
A. Not until pressed.
Q. What do you mean by "pressed"?
A. Customer complaints.
Q. Did ZHP identify unknown peaks that it failed to follow up on?
A. Are you talking about all peaks that could --
Q. Any unknown peaks. I'm trying to understand the basis for your opinions. Are you offering an opinion that ZHP identified unknown peaks and then failed to follow up and try to figure out what they were?
A. It's my understanding that ZHP knew of the peaks since as early as 2014, and did not identify the NDMA peaks.
Q. Did ZHP follow up whenever a customer identified an unknown peak to try to determine what it was?
A. There were responses to the customer

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complaints.
Q. And did those responses reflect efforts by ZHP to test the unknown peaks and determine what they were?
A. From what I read, there were investigations performed but there was no identification of the NDMA peaks.
Q. And why were there no identifications of the NDMA peaks?
A. I don't know that.
Q. Are you qualified to opine on the adequacy of ZHP's testing of unknown peaks?
MR. SLATER: Objection. Qualifications is a legal question. It's a totally inappropriate question.
You can answer.
A. As to whether or not -- can you please read the question again now?
Q. Do you consider yourself to be qualified to testify, to offer an opinion on whether ZHP's testing of unknown peaks was adequate?
A. Yes.
Q. And what is your qualification to evaluate an API manufacturer's testing of unknown peaks?

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MR. SLATER: Objection. This is a legal conclusion and a legal argument. You have her background and her qualifications. Do you have a specific question you want to ask?
Q. Do you need David to repeat the question?
A. Yes, please.
MS. MILLER: David, please go ahead.
(Record read.)
A. I would say my background and training in auditing and in the ICH and FDA guidelines that address risk assessment.
Q. Have you ever done a risk assessment for unknown impurities in a product?
A. I personally have not performed a risk assessment for unknown impurities.
Q. Have you ever been retained by a client to look at their risk assessment and determine whether it was adequate in terms of how it was testing for unknown impurities?
A. Not specifically for unknown impurities.
Q. Is that a task that would be more appropriately accomplished by a chemist?
MR. SLATER: Objection.
You can answer.

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A. In the normal course, what would happen is, I would do an assessment and if we got to a point where the organic chemist as an SME subject matter expert would need to give input, I would pull an SME in for his or her advisement.
But I would do the overall risk assessment.
Q. How can a non-chemist determine whether a risk assessment for unknown impurities is adequate?
MR. SLATER: Objection.
You can answer.
A. I would rely on the guidance documents. We know that it, the guidance documents require the firms to test for unknown impurities. And I would simply ask, have you addressed the unknown impurities as required in the various guidance documents?
Q. Is the manufacturer under the guidance required to identify unknown impurities below a certain threshold?
MR. SLATER: Objection.
You can answer.
A. Companies are required to investigate all unknown peaks.
Q. And where does it say that?
A. It says that in the ICH M7. The -- Q3,

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"Impurities in new drug substances."
Q. Can you tell me what you're reading from?
A. I'm not reading from anything.
Q. Oh, you just turned to the side like you were reading from something.
A. No, I was thinking. I'm sorry, I was thinking.
Q. Okay. So continue with my question.
MR. SLATER: I'm sorry, she was in the middle of an answer, then you asked her why she was looking at the side. Just for the record, you cut her answer off. I'm just making it clear for the record.
MS. MILLER: Happy for her to continue.
MR. SLATER: After you cut her off, and completely cut the entire train of thought, but that's okay.
Q. Would you like to continue?
A. I've lost my train of thought now.
Q. So let's start with the question again.
MS. MILLER: David, do you want to repeat the question?
(Record read.)
MR. SLATER: Could you read back her

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answer please, up to the point where it was interrupted so she can hear what she said, please?
(Record read.)
Q. So it's your testimony that ICH M7 and Q3 require a company to show --
MR. SLATER: I'm sorry, what are we doing? She hadn't finished her answer. Now she had it read back to continue answering. Now you don't want her to do that anymore, now you're on to a new question? Just confirming what we're doing. You're now on to a new question after cutting off her last answer.
MS. MILLER: As David read back, she testified that ICH M7 and Q3 require a manufacturer to address all unknown peaks.
Q. Are there any other documents that you believe require manufacturers to address all unknown peaks?
A. ZHP has their own internal SOP, and regarding impurities, and the need to evaluate those impurities.
Q. Is a manufacturer required to investigate the identity of an impurity that is below a certain threshold?
A. Yes.

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Q. Is there a threshold below which a manufacturer does not have to identify unknown impurities?
A. No.
Q. Does ICH Q3 apply to manufacturing changes or only to new drug substances?
A. Changes as well.
Q. Does ICH Q3(a) state that there's no need for a new drug applicant to test for impurities under a certain level?
MR. SLATER: Objection, lack of foundation. You can answer.
If you want to show her a specific question and ask her what that means, that would be a fair question as opposed to this memory test you're doing. But you can ask the question, and whether you can use them or not, it's fine, but I think it's -- and I have a serious issue with lack of foundation and mischaracterization, something I'm looking at.
Q. Do you know whether ICH Q3(a) recognizes that there's no need for a new drug applicant to test for trace level impurities under a certain level?
MR. SLATER: Objection, lack of foundation. Same objection.
You can answer.

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A. I would have to look at ICH Q3.
Q. Do you agree that when evaluating a compound for toxicity, it's important to know whether the compound has been shown to be harmful in humans?
MR. SLATER: Objection.
You can answer.
THE WITNESS: Can you read that question back? I'm sorry.
Q. Do you agree that when evaluating a compound for toxicity, it's important to know whether the compound has been shown to be harmful in humans?
MR. SLATER: Objection.
You can answer.
A. It does not matter whether it's been found to be harmful in humans.
Q. Did ZHP perform a science-based assessment of its processes?
MR. SLATER: Objection. Massive vagueness, lack of foundation. Lack of necessary terms to ask a question that can be intelligibly answered.
Subject to those objections, you can answer.
A. Whether or not they did a literature search --

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Q. Did ZHP perform a science-based assessment of its processes for manufacturing Valsartan?
MR. SLATER: Same objection.
A. Whatever analysis was done was inadequate.
Q. So is it your opinion that they performed a science-based assessment but it was not adequate because it did not find NDMA?
MR. SLATER: Objection.
You can answer.
A. Yes.
Q. Does compliance with CGMPs turn on what is reasonably known at the time the product is being manufactured?
MR. SLATER: Objection, lack of foundation. Vague. Ambiguous.
You can answer.
A. I'm sorry, I cut out right in the middle, can you please --
Q. Sure. Does compliance with CGMPs turn on what is reasonably known at the time the product is being manufactured?
A. I missed one word in the middle, it sounded like "turn."

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Q. Um-hum.
A. Does manufacturing -- I'm sorry, just read it to me again, now --
Q. Does compliance with CGMPs turn on what is reasonably known at the time the product is being manufactured?
A. I'm sorry, I don't understand what you mean by "turn."
Q. Does the manufacturer's compliance with CGMPs -- is a manufacturer's compliance with CGMPs based on what is reasonably known at the time the product is being manufactured?
A. Yes, and all prior scientific knowledge.
Q. Did the FDA ever ask ZHP to use separate workshops for different manufacturing processes?
A. I don't know that answer.
Q. Is using the same workshop for different manufacturing processes a CGMP violation?
MR. SLATER: Objection. Incomplete hypothetical, lack of foundation.
You can answer.
A. It is acceptable to use the same facility to manufacture different products as long as there's adequate validation or cleaning and segregation.

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Q. And where is that written?
A. That's GMP. It's just, all processes must be validated and all processes have to be -- I'm sorry, all cleaning processes have to be validated.
Q. While you were at the FDA, did you ever investigate whether cross-contamination occurred at a manufacturing facility?
A. No.
Q. In the course of your work in the private sector, have you ever made a determination that manufacturing lines were cross-contaminated?
A. No.
Q. In the course of your consulting, have you ever advised a client on cross-contamination?
A. I've advised on the potential for cross-contamination.
Q. Do you consider yourself to be an expert on the questions and issues of cross-contamination in pharmaceuticals?
MR. SLATER: Objection, same reasons I objected to questions about qualification before.
But you can answer, Dr. Bain.
A. Yes.
Q. And what is the basis for that expertise?

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A. I've been involved with validation of cleaning processes.
Q. What do you mean by that?
A. I had quality engineers working for me that wrote validation protocols and validation reports with regards to cleaning validation.
Q. Did the FDA inspect manufacturing facilities for API?
A. Yes.
Q. Do you know how many times the FDA inspected ZHP's facilities between 2010 and 2018?
A. No, I don't.
Q. Did you review the results of the FDA's inspections of ZHP facilities between 2010 and 2018?
A. I did review some. I don't know if that entailed all. That was done at all their facilities.
Q. Do you know whether the FDA's inspections of ZHP facilities between 2010 and 2018 resulted in any official regulatory actions?
A. They put -- FDA put ZHP under an import alert and they issued -- FDA form 483s, and they issued a warning letter.
Q. Prior to the recall of Valsartan, do you know how many inspections there were of ZHP manufacturing facilities by the FDA?

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A. I do not know off the top of my head, no.
Q. Between 2010 and the recall, do you know whether any FDA investigation of a ZHP facility resulted in official regulatory action?
A. The dates again, please?
Q. Between 2010 and the date of the recall, do you know whether any FDA inspections of ZHP manufacturing facilities resulted in official regulatory action?
A. Yes.
Q. Is it your testimony that there was official regulatory action between 2010 and the time of the recall?
A. I would need to go back and look at the dates.
Q. When you said yes, what were you referring to?
A. I was referring to the inspections that took place in the 2018 time frame.
Q. Right, but I'm asking prior to the recall, were there any inspections of ZHP manufacturing facilities that resulted in official regulatory action?
A. I would have to go back and look.

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Q. Did the warning letter and import alert occur before or after the recall?
A. Import alert and warning letter. Now you're asking specific dates. I would have to go back and look at the specific dates of the actual -- first recall, and the date of the warning letter and the date of the import alert.
Q. Would it surprise you to know that there were ten inspections of ZHP's facilities between 2010 and the date of the recall and that none of them resulted in official regulatory action?
MR. SLATER: Objection, foundation.
You can answer.
A. It wouldn't surprise me necessarily.
Q. If there was no official regulatory action taken at any ZHP facility between 2010 and the time of the recall, what does that mean, that the FDA -- does that mean that the FDA did not find any objectionable conditions or practices that justified regulatory action?
MR. SLATER: Objection. Lack of foundation. Incomplete hypothetical.
You can answer.
A. It means when they performed the inspection, they -- the inspection areas they

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covered, they were not -- they did not find anything objectionable.
Q. Aside from the FDA, do you know whether any other regulatory authorities inspected ZHP facilities between 2010 and the time of the recall?
A. I would have to look at the date of the EMA inspection.
Q. Are you aware of any other inspections that occurred?
A. No, I'm not.
Q. Are you aware of what BGV is?
A. No, I'm not.
Q. Did ZHP's customers also conduct on-site audits of ZHP?
A. I'm not aware of any.
Q. Do you know how many customer audits occurred between 2016 and 2018 at the ZHP manufacturing facilities?
A. No, I don't.
Q. Do you address that in your report?
A. No.
Q. Are you aware that Teva routinely audited ZHP facilities?
A. No, I'm not aware of that.
Q. Did you address that in your report?

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A. No, I did not.
Q. If you're not aware of the audit, I take it you're not aware of what the results were of Teva's audits or the audits of other customers between 2010 and 2018, is that correct?
A. Yes, that's correct.
Q. And are you aware that Novartis inspected ZHP approximately 13 times between 2010 and the date of the recall in 2018?
A. No, I was not aware.
Q. Do you know whether ZHP passed those audits?
A. No, I don't.
Q. And was that addressed in your report?
A. No, it was not.
Q. Are audits by customers relevant to your opinions in this case?
MR. SLATER: Objection.
You can answer.
A. I'm sorry, are they relative to what?
Q. Relevant to your opinions.
MR. SLATER: Objection, lack of foundation, incomplete hypothetical.
You can answer.
A. Can you please read the question back?

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MS. MILLER: Go ahead, David.
(Record read.)
A. No.
Q. Why not?
A. Because I was evaluating their compliance to CGMPs.
Q. Are you aware that Novartis stated in one of its audit reports in 2017 that ZHP has a sufficiently good quality system to manufacture non-sterile APIs according to ICH Q7?
MR. SLATER: Objection, you can answer.
A. No, I wasn't.
Q. And you did not review any discussion of any audits of ZHP's manufacturing processes including any references in those audit reports to ICH compliance during the period 2010 to 2018, correct?
MR. SLATER: Objection.
You can answer.
A. You're speaking of the customer audits?
Q. Correct.
A. I did not discuss anything related to customer audits.
Q. And therefore, you don't know whether the customer audits addressed ZHP's compliance with ICH standards, correct?

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A. That's correct.
Q. And the same would go for Eli Lily's audits of ZHP's manufacturing facility, correct?
MR. SLATER: Objection.
You can answer.
A. Yes, that's correct.
Q. What steps should ZHP have taken in its risk assessment that it did not take?
MR. SLATER: Objection.
You can answer.
A. They didn't fully assess the potential reaction that led to the formation of the NDMA.
Q. What should they have done that they didn't do?
MR. SLATER: Objection, form.
A. They should have addressed the chemistry. If they did see unknown peaks during development, those should have been assessed as well.
Q. Do you know whether ZHP conducted a risk assessment that looked at the chemistry?
A. Not to my knowledge.
Q. Do you know whether ZHP looked at unknown peaks as part of its risk assessment?
A. Not to my knowledge.
Q. Do you know what ZHP did in its risk

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assessment?
A. Not completely.
Q. Would it be relevant to your opinion to understand what ZHP did in its risk assessment?
A. No.
Q. All right.
MS. MILLER: I need a break. Let's go off the record. My throat is killing.
VIDEOGRAPHER: The time is 1:05. This ends media unit number 4. We're going off the record.
(Recess taken.)
VIDEOGRAPHER: The time is 1:24. This begins media unit number 5. We're back on the record.
EXAMINATION (Cont'd.)
BY MS. MILLER:
Q. You say in your report that ZHP failed to implement and adequately apply its own internal SMPs, correct?
A. Yes.
Q. What internal SMPs did ZHP fail to implement and adequately apply?
A. Okay to me to answer now?
Q. Yeah, we're waiting.

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A. Oh.
MR. SLATER: You can answer.
A. Okay. ZHP has an internal SOP on genotoxic impurity evaluation. That was not followed.
Q. In what way did ZHP not follow its internal SMP on that?
A. They were to identify unknown impurities. Additionally, they didn't do an adequate job on their risk assessment to identify the potential for NDMA to be formed.
Q. You're saying that ZHP's risk assessment violated its own SMPs?
A. They didn't do an adequate job. They didn't find it. They didn't adequately assess the scientific literature that was available.
Q. Would any risk assessment that failed to find the NDMA and NDEA have been inadequate?
A. Yes.
Q. What scientific literature did they not follow?
A. Various --
MR. SLATER: Objection to the form of the question.
You can answer.

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A. As discussed in my report, there were several instances of testimony where the person being deposed said that they did not assess scientific literature.
Q. You're saying that ZHP witnesses testified that they did not assess scientific literature?
A. Yes.
Q. They said they did not assess any scientific literature, or they said they didn't assess the two articles that counsel provided to you?
MR. SLATER: Objection regarding the two articles, lack of foundation, mischaracterization.
You can answer.
A. I think we need to go back to those portions of the report. They didn't say the specific articles or documents. They didn't assess. They merely said they didn't do a good scientific assessment. They did not assess the literature.
Q. You're saying that ZHP witnesses said they did not do a good scientific assessment?
A. Again, let's -- you know, if we want to go to the report, we can go to the report and find the specific areas where they discussed their assessment.

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Q. Do you recall which witnesses you're talking about?
A. Not without going back and looking at the report.
Q. Did you review ZHP's process change request?
A. Yes.
Q. Was it adequate?
A. No.
Q. What was inadequate about ZHP's process change request?
A. They didn't address the unknown peaks.
Q. When you say they didn't address the unknown peaks, what do you mean?
A. When there's a process change, it has to be a full risk assessment done and this assessment should have included the analysis that would have led to the knowledge of the NDMA formation. And that was not addressed in their change request.
Also not addressed in their change request was that they were making the change to save money.
Q. What change was made to save money?
A. The zinc chloride, I believe.
Q. Is that the only reason that change was

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made?
A. I can't say that that was the only reason. But we have testimony about one person telling the FDA during an inspection that the change was made so they could manufacture more product and dominate the world market.
Q. Is manufacturing more product the same thing as saving money?
A. It is not the same thing as saving money.
Q. I thought you said --
A. I'm sorry, go ahead.
Q. Go ahead. I thought you were done.
A. My recollection, it was both, but the person -- the person, and I believe it was Mr. Du, we can again go back to the report and confirm that, who told the FDA investigator that the main reason for the change in the manufacturing process was to increase yield and dominate the world market.
Q. Was that the zinc chloride process or the TA process?
A. I'm sorry?
Q. Is that the zinc chloride process or the TA process with quenching?
A. The zinc chloride.

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Q. So it's your testimony that the zinc chloride process was implemented to increase yield and also to reduce cost?
A. I'm telling you what the gentleman said to the FDA.
Q. Is it your testimony that it had both those purposes?
A. I'm sorry, is it my testimony that?
Q. It had both of those purposes, the two purposes you said?
A. I'm only telling you, and again, we can go to my report, because I have it in there, it's cited, that he said increasing yield and dominating the world market.
Q. A few minutes ago you testified about lowering costs. I'm trying to understand where that comes from.
A. I may have misspoken on the lowering costs. Again, I have to go back to my report. There's a lot of information in there and we can go back and look.
Q. Do you know why the TA process was implemented, the TA with quenching?
A. I believe that had to do with addressing some environmental concerns. But again, we could go

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back to the report.
Q. Did FDA use the term "critical change"?
A. The FDA -- again, I need to go back to FDA's website specifically. They generally categorize changes as major, moderate and minor.
Q. ZHP submitted Drug Master File amendments with respect to the two changes at issue in this litigation, correct?
A. Yes.
Q. Oh, by the way, do you know how the TA with quenching process led to the formation of NDEA?
A. Look at the DMF degradation to DMA, and then sodium nitrite, the quenching and then NDEA formation.
Q. Is that the zinc chloride process or the TA process?
A. Again, I have to go back and look to make sure.
Q. Would any ANDA submissions that were made for generic Valsartan after ZHP submitted its master files have incorporated those Drug Master Files?
A. Could you repeat that?
Q. Does the FDA review Drug Master Files in connection with ANDAs?

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A. Yes.
Q. And was ZHP's Drug Master Files subsequently incorporated into ANDAs?
A. Yes.
Q. Did you review ZHP's Drug Master File amendments?
A. Yes, briefly.
Q. Did they include assessments of the risks of each process?
A. Not adequately.
Q. Did they address any assessment of the risks of each process?
A. Yes.
Q. Did they include results of chromatography testing documenting impurities that resulted from each process?
A. I'd have to go back and look.
Q. Do you know sitting here today whether the Drug Master Files included the results of chromatography testing that documented impurities?
A. Again, I'd need to go back to the DMFs themselves just to see if the chromatography charts were there.
Q. Is there any evidence that FDA chemists expressed concerns about the TA with quenching

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process or the zinc chloride process prior to ZHP's June 2018 self report of the findings?
A. Not to my knowledge --
MR. SLATER: Objection -- one second -- objection, lack of foundation.
You can answer.
Q. Did any FDA chemist ever come to ZHP and say, "Hey, DMF degrades and we're worried about your use of DMF as a solvent"?
A. Not to my knowledge.
Q. Did anybody from FDA ever express concern to the ZHP that it was using TA with quenching?
A. I have no way of knowing that.
Q. Did you review ZHP's risk assessment for the DMF amendment with respect to zinc chloride process?
A. Yes.
Q. Other than the failure to identify NDMA, was there something about that risk assessment that you found to be inadequate?
MR. SLATER: Objection.
You can answer.
A. Other than they didn't do an adequate risk assessment, that would be the major thing that

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came out to me.
Q. And when you say it wasn't an adequate risk assessment, that's solely because NDMA was not identified, correct?
A. Correct.
MR. SLATER: Objection.
You could answer.
Q. Did ZHP's risk assessment include evaluating process changes?
A. Yes.
Q. Did ZHP consider the suitability of specifications and analytical substance evaluation?
A. They said -- I believe they said they did.
Q. Did ZHP evaluate the manufacturing equipment?
A. Yes.
Q. Did ZHP compare the use and quantity change of raw materials, synthetic roots, process description and critical process parameters between the two processes?
MR. SLATER: Objection.
You can answer.
A. They didn't address the critical process that led to the NDMA formation.

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Q. What's a critical process?
A. A process which could affect final container product -- I'm sorry, final container product quality.
Q. What did ZHP's risk assessment state with respect to impurities?
A. Again, if we can pull it up, that would be great.
Q. Do you recall what ZHP concluded with respect to impurities?
A. They didn't see any impurities that were cause for concern.
Q. Did ZHP identify the -- quantify the level of unknown impurities in the product?
MR. SLATER: Objection.
You can answer.
A. I don't remember.
Q. Did ZHP confirm that the quantity of unknown impurities was below a certain threshold?
MR. SLATER: Objection.
You can answer.
A. I believe they did but again, to say for sure, we should pull it up.
Q. Did ZHP conduct the change committee assessment and a QA final approval?

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A. Yes.
Q. Did ZHP state that it was making these changes to improve its manufacturing process?
A. I honestly don't remember what the exact verbiage was in the change control.
Q. At any time prior to 2018, did the FDA tell manufacturers that they should be looking for NDMA and NDEA?
MR. SLATER: Objection.
You can answer.
A. The FDA expects industry to at all times assess for genotoxic and carcinogenic impurities.
Q. Did the FDA, prior to 2018, ever specifically call NDMA and NDEA as things that manufacturers should be looking for?
A. I don't know of all the correspondence or all their interactions with all firms. There's no way I can answer that.
Q. Did the FDA, subsequent to the recall in 2018, issue guidance on levels for NDMA and NDEA in drug products?
A. Yes.
Q. And what is the current requirement issued by the FDA with respect to NDMA or NDEA in drug products?

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A. We could go to the source and verify. But I believe it's 0.3 ppm of NDMA, and NDEA is something at .08; but again we should go and pull the -- the guidance document and view the actual numbers.
Q. Are you offering an opinion in your report that ZHP did not conduct a scale-up process from lab scales for pilot scale to commercial scale?
A. Yes.
Q. Does the FDA require a manufacturer to have a pilot scale?
A. Yes.
Q. Where does the FDA state that a manufacturer must have a pilot scale and can't test its product at the commercial scale?
A. I would have to go to the ICH guidance documents, but I believe in the -- let me think first -- I believe that ICH Q8 -- but again, we need to pull these ICH documents up, you know, I -- I can't remember verbatim which statement is in which document.
Q. Is it your opinion that there is an ICH document that states that a manufacturer has to use the pilot scale for -- as its technical batch, as opposed to using commercial scale as its technical batch?

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A. There is in some guidance, but again, we can pull them up one by one and go through them. But FDA does expect that you do a stepwise process as you're developing your product and scaling it up. Doing your risk assessments, I'm sorry.
Q. If you use the commercial scales instead of the pilot scale as your technical batch, what's the downside of that?
A. Then you're asking if you skipped all the other scale-ups in between?
Q. If you just skipped the pilot scale -- your testimony is that ZHP skipped the pilot scale. And I'm asking you, what's the consequence of skipping the pilot scale and using the commercial scale as your technical batch?
A. You haven't had a chance to adequately assess risks and -- excuse me, of the product and as a manufacturer of the process.
Q. The commercial scale just means you've made more of it, right?
MR. SLATER: Objection.
You can answer.
A. Means you've made a larger batch size. So...

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Q. So if you end up testing on the commercial batch instead of the pilot batch, the only outcome is you may have more to throw away, right?
MR. SLATER: Objection.
You can answer.
A. No, as I said, you are missing the opportunity to perform risk assessments on your test methods, on your processing capabilities, on your actual final container specification. So there's a number of areas that that would be impacted by that.
Q. Does ZHP not perform those assessments, or to they just perform those assessments on the commercial batch?
A. Not perform those assessments why?
Q. You just said a bunch of things that you said you'd be skipping. And I'm asking you, did ZHP not perform those assessments, or did they just perform those assessments at the commercial scale?
A. I don't know what else they did during their development. Their bench scale, I don't know what they did at that point.
Q. Was there testimony from ZHP that they were able to use the commercial scale as the technical batch to replace the pilot scale?
A. Yes, I do believe I read that.

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Q. And is it your opinion that that violates CGMP?
A. When you say "commercial batch," to me, I need a definition of what you mean by "commercial batch." To me, commercial batch is, it's approved and it's something that you're already putting out on the market. It's in interstate commerce.
Q. So when you refer to the Gu deposition and he testified that ZHP uses the commercial scale as the technical batch to replace the pilot scale, it's your understanding that it wasn't tested before it was sold or it's your understanding that they just tested it using a larger scale?
A. I don't know what the scale was of that batch.
Q. But are you nonetheless offering an opinion that this was a CGMP violation?
A. That they used a technical -- what they define a technical batch? I'm sorry, I don't know what a technical batch is. I'm not familiar with that.
Q. You stated in your report, citing Dr. Gu, that they used a scale-up process that was improper.
I'm asking if you're offering the

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opinion that ZHP engaged in CGMP violations with respect to the way it scaled.
MR. SLATER: By the way, objection. One second. Objection to the foundation with the very inaccurate paraphrase of the summary of the testimony of Mr. Gu in the report.
You can answer the question.
MS. MILLER: Actually, I used a quote, but go ahead.
MR. SLATER: No, I don't think you did, actually.
MS. MILLER: Okay, go ahead.
MR. SLATER: Not from the report, you didn't.
A. So the report that was generated from Syncores regarding the development of the zinc chloride process stated that ZHP needed to do a pilot batch.
Q. Dr. Gu testified that ZHP was able to use the commercial scale as the technical batch to replace the pilot scale. That was his testimony. I'm asking you if that violated CGMP principles. That's all I'm asking.
MR. SLATER: Objection to the foundation, but you can answer the question.

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A. Again, what -- please tell me what a technical batch, so --
Q. I'm reading his testimony. That's a direct quote.
MR. SLATER: I'm sorry, what testimony are you reading? Do you want to share it, please, because I don't think it's appropriate to read the testimony without showing it --
MS. MILLER: I just want to --
MR. SLATER: -- no, no. I'm objecting and your interrupting me. We're doing -- what you're doing is inappropriate. I'm asking you, if you want to talk about testimony, tell us the pages and lines from the transcript. Let her have it.
And I think that you're misrepresenting what's in her report, too, in terms of what's cited in her report. I think that the questioning has been very confusing and unfair and you can't just rattle off, "He said this, he said that." We have the right to know what part of the deposition you're referring to, if you're going for refer to his deposition.
So please either tell us where you're reading from so we can look at it, or move on to another question, please.
Q. Are you offering an opinion that ZHP

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violated CGMP principles and regulations with respect to the scale-up process?
MR. SLATER: That's already been asked and answered.
MS. MILLER: Hasn't been answered.
MR. SLATER: Okay, you can answer it again, Dr. Bain.
A. Yes.
Q. Are you aware of any customer complaints between 2014 and 2018 involving unknown peaks that ZHP did not follow up on?
A. I'm aware of customer complaints that did have follow-up. I am not aware of all of their customer complaints or whether I reviewed all of their customer complaints. I didn't receive a customer complaint log listing all of their complaints.
Q. Did you ask Plaintiffs' counsel to provide you with all the complaints that were submitted to ZHP?
A. All the complaints that were?
Q. Submitted to ZHP from customers.
MR. SLATER: Objection.
You can answer.
A. I did not ask for every complaint that

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every customer made to ZHP.
Q. Do you recall seeing any customer complaint that ZHP did not follow up on?
A. When you say follow-up, are you talking about respond?
Q. Respond and conduct testing.
A. The complaints I saw did have a response from ZHP.
Q. Are you offering an opinion that Valsartan APR was adulterated?
A. Yes.
Q. When did you first form that opinion?
A. When I heard about it through reading or the news.
Q. So you formed that opinion that Valsartan was adulterated before you were approached to be a witness?
A. Yes, because it was recalled.
Q. Is it your opinion that every recalled drawing is adulterated?
A. No.
Q. So what was the basis of your opinion that Valsartan API was adulterated prior to being retained as an expert in this litigation?
A. It was because in the news it was stated

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that it was being recalled for contamination with NDMA.
Q. Is it your opinion that any pharmaceutical drug that is recalled based on an impurity is adulterated?
MR. SLATER: Objection.
You can answer.
A. If a drug contains material that has not been identified or is not on the labeling, then yes, it would be adulterated.
Q. So any drug that contains an impurity that's not identified on the labeling is adulterated?
A. Not necessarily on the labeling. It has not been addressed properly and assessed to ensure that there's no effect on finished product quality.
Q. So any drug with an unknown impurity that has not been assessed you would consider to be adulterated?
A. Yes.
Q. And what is that based on? Is that based on a regulation or guidance or what?
A. Definition of "adulterated."
Q. Do you understand the definition of "adulterated" to mean any drug with an unknown impurity that has not been investigated?

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A. Adulterated --
MR. SLATER: Will you let her look at the regulation?
MS. MILLER: She's in the middle of answering the question.
MR. SLATER: This whole deposition, I'm just making an observation, she's allowed to consult the documents.
MS. MILLER: You can show her all the documents you want on direct.
MR. SLATER: Thank you --
Q. Do you know what "adulterated" means without looking at the FDA regulations?
A. When a drug or a product, let's say, does not meet quality, purity, identity or strength that it's purported to have.
Q. And would a product that has an unknown impurity of any level be adulterated?
MR. SLATER: Objection. Hopelessly vague question. Lack of foundation.
You can go ahead and try to answer it.
A. If a product has an unknown impurity and the firm has not investigated that impurity to see whether it has an effect on final product quality, then yes, it would be adulterated.

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Q. So if Diovan had NDMA or NDEA impurity, would it be adulterated?
MR. SLATER: Objection. Incomplete hypothetical.
You can answer.
A. Diovan as it was approved did not have NDMA in it. So if it did have NDMA in it, it wouldn't be Diovan.
Q. If Diovan was sold with NDMA impurities, was it adulterated?
MR. SLATER: Did you say "if"?
MS. MILLER: I did.
MR. SLATER: You can answer the question.
A. Yes.
Q. Is your sole basis for believing that Valsartan was adulterated the fact that it contained NDMA and NDEA?
A. Well, there were other issues as well but it was adulterated because it contained NDMA and NDEA.
Q. And what reports led you to that conclusion?
A. As I said in earlier testimony, I don't know where I read or heard about the original recall

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and the contamination with NDMA and NDEA.
Q. Is contamination the same thing as an impurity?
A. No.
Q. Was Valsartan contaminated with NDMA or did it have an NDMA impurity?
A. Impurities.
Q. If SOMEONE used the word "contamination," was that erroneous?
A. Impurities are contaminants, but contaminants are not all impurities. You might have a contaminant in a drug that's a piece of glass from a vial, and it would be contaminated. But it didn't have the drug -- the drug itself didn't have an impurity.
Q. Was Valsartan contaminated with NDMA or did it have an NDMA impurity?
A. It had an NDMA impurity.
Q. Is it your opinion that any time a generic drug has an impurity that's not present in the RLD, that there is a CGMP violation?
MR. SLATER: Objection.
You can answer. Complete lack of foundation, incomplete hypothetical.
Q. Do you need the question repeated?

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A. No, I'm thinking.
Q. Okay.
A. You're asking if a generic has an impurity, was there a GMP violation?
Q. That's not present in the RLD, I think I said.
A. That's not in the RLD. Yes.
Q. And if every time a generic drug has an impurity that's not present in the RLD, is that generic drug adulterated?
A. Yes.
MR. SLATER: Objection, asked and answered. You can answer again. You said yes? Okay.
THE WITNESS: Yes, I said yes.
Q. Are all drugs that use API from a facility that's out of compliance with CGMP adulterated?
MR. SLATER: Objection, incomplete hypothetical, lack of foundation.
You can answer.
A. Could you repeat that question?
Q. Are all drugs that use API from a facility that's out of compliance with CGMP adulterated?

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A. Not necessarily.
Q. Does the impact of CGMP violations affect whether or not -- hold on, let me put that differently. Does the severity of CGMP violations affect whether a drug is adulterated?
A. No.
Q. Does the frequency of CGMP violations affect whether a drug is adulterated?
A. No.
Q. Is an adulterated drug necessarily unsafe?
A. No.
Q. When was Valsartan first adulterated?
A. Are you asking for a date?
Q. Um-hum.
A. I'm sorry, I'd have to go back and look at the dates that they introduced the product into interstate commerce. I don't know that off the top of my head. Somewhere in the -- I don't know, 2015 range.
Q. Is it your opinion that subsequent to that time, every lot of Valsartan API was adulterated?
A. Yes.
Q. Has the FDA ever stated that warning

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letters are not appropriate in certain situations?
MR. SLATER: Objection.
A. I'm sorry, that's very vague.
Q. Does the FDA -- do the FDA's regulations state that warning letters are inappropriate when a violation is intentional or flagrant?
MR. SLATER: Objection.
You can answer.
A. I have not seen that written.
Q. Has FDA ever stated that warning letters are not appropriate when the violation presents a reasonable possibility of injury or death?
A. Not to my knowledge.
Q. Has FDA ever stated that warning letters aren't appropriate when there's a history of repeated or continual conduct of a similar or substantially similar nature?
A. Not to my knowledge.
Q. If a company takes corrective action, what does the FDA do with respect to the warning letter?
A. If the company takes corrective action, generally, they will notify the FDA that they have taken the corrective action and are ready for a reinspection. FDA will go out and reinspect and

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assess whether the corrective action was adequate.
Q. And what happens if the corrective action was adequate?
A. They will close the warning letter.
Q. Was the warning letter at issue here closed?
A. Yes.
Q. Are you offering an opinion that Valsartan API did not meet USP requirements?
A. Yes.
Q. What is that based on?
A. The fact that it was contaminated with NDMA and NDEA.
Q. Did we just establish a few minutes ago that "contaminated" isn't the right word there?
MR. SLATER: Argumentative. Objection. You can answer.
A. As I said, contaminated -- sorry, all impurities would render a drug contaminated, but a contaminated drug does not necessarily contain an impurity. So in other words, I'm saying, contaminated in a general sense.
Q. Did Valsartan API comply with the compendial description of the drug?
A. When it was manufactured using the TIN

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process.
Q. Did the USP compendium reference unknown impurities?
A. The USP reference --
Q. To Valsartan standard.
A. Not to my knowledge.
Q. Did you review the USP Valsartan standard?
A. Yes.
Q. And does that standard reference unknown impurities?
A. Can we pull that up, please?
Q. Is it your opinion that any impurities in Valsartan would have failed to satisfy the USP Valsartan standard?
A. Again, I'd like to take a look at the standard.
Q. Okay. But are you offering an opinion in this litigation that any Valsartan with impurities would not have complied with the Valsartan standard?
MR. SLATER: Objection, form.
A. I'm saying -- I'm saying Valsartan with NDMA would not meet USP.
Q. And why wouldn't Valsartan with NDMA meet USP?

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A. Because Diovan was approved, the RLD was approved without NDMA.
Q. So if Valsartan had any impurities at any level whatsoever, that were not found in Diovan, is it your opinion that it wouldn't have satisfied the Valsartan USP?
MR. SLATER: Objection, lack of foundation, hopelessly vague and ambiguous, overbroad, and incomplete hypothetical.
Q. Do you need --
MR. SLATER: You can answer that question if you'd like.
MS. MILLER: Do you want me have David read that question back.
THE WITNESS: I would like that.
MS. MILLER: Okay, David, could you please read back the question.
(Record read.)
MS. MILLER: USP standard.
A. If Valsartan had impurities that Diovan did not have, it would not meet Diovan USP.
Q. Are you aware that Section 5.60.10 of USP 35 states a manufacturer need not identify and include on its label any impurity, provided that the impurity is less than 0.1 percent of the content of

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the drug substance?
MR. SLATER: Objection. You want to show it to us? Object, lack of foundation. Ask that you actually show the section that you're talking about. It's the whole thing.
Q. Are you aware of any statement in the USP 35 that a manufacturer does not need to identify and include on its label any impurity that's less than 0.1 percent of the content of the drug substance?
MR. SLATER: Same objection.
A. If you pull up the USP we'll take a look.
Q. I'm asking whether you know, as an expert sitting here today, do you know whether USP states that a manufacturer doesn't have to identify an impurity that's less than 0.1 percent.
MR. SLATER: Objection, counsel --
Q. Do you know or not?
MR. SLATER: I'm sorry, you're not going to let me talk? She heard --
MS. MILLER: You interrupted me.
MR. SLATER: Well, you interrupted my interruption of your interruption.
MS. MILLER: Excuse me, I was in the

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middle of asking a question.
MR. SLATER: And she has said now twice she'd like to see the section --
MS. MILLER: I heard her, and I'm asking my own question, which I'll ask again.
Q. Without looking at any USP documents, do you know whether USP states that a manufacturer doesn't need to identify and include on its label an impurity that's less than 0.1 percent of the content of the drug substance?
A. Without looking at the USP, I do not know.
Q. Okay. Do you know whether any Valsartan had NDMA or NDEA at a level of 0.1 percent or more?
A. Yes.
Q. Did any single batch of Valsartan API contain NDMA or NDEA at a level of 0.1 percent or more of its content?
A. Can we please pull up? There's data showing the testing that was done in the DIL. If we could look at that, we could verify the numbers.
Q. So I don't know what you're referring to, but I'm just asking, do you know sitting here today whether any Valsartan contained NDMA or NDEA at a level of more than 0.1 percent?

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A. Again, yes, it did.
Q. And was that NDMA or NDEA?
A. Again, can we pull up the data? The tests were done and as I sit here, I don't know if it was NDMA, NDEA but again, if we could refresh with the data, it would be quick to see.
Q. Under the USP, do you know what the maximum level is for combined impurities?
A. No --
MR. SLATER: One second. Are you talking about combined genotoxic, cohort of concern impurities, or all impurities in the world? Can you refine your question, please? It's hopelessly vague --
MS. MILLER: Thank you for your testimony.
MR. SLATER: It's not testimony. I'm just asking you at some point to ask a straightforward question.
Q. Do you know if UPS states that unknown impurities cannot exceed in combination a specific threshold?
A. I don't know if that's specifically stated in USP.
Q. Thank you. Is there any USP monograph

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to your knowledge that mentions nitrosamine impurities7?
A. Not to my knowledge.
Q. Does every generic drug have an identical impurity profile to its RLD?
A. To my knowledge, they do.
MR. SLATER: Can I have that last question and answer read back to me, please?
MS. MILLER: David.
(Record read.)
MR. SLATER: Thank you.
MS. MILLER: Let's go off the record. I think I have about an hour left and I want to figure out where to go from here in terms of finishing up on time.
VIDEOGRAPHER: The time is 2:19. This ends media unit number 5. We're going off the record.
(Discussion off the record.)
(Recess taken.)
VIDEOGRAPHER: The time is 2:41. This begins media unit number 6. We're back on the record.
(Continued on following page.)
EXAMINATION (Cont'd.)

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BY MS. MILLER:
Q. Are there acceptable limits for NDMA impurities in Valsartan currently?
A. NDMA is one of the cohort of concern where there is no threshold for NDMA; however, FDA has instituted a level of concern -- I'm sorry, a level of acceptance.
Q. If Valsartan is sold with NDMA below that level, is it adulterated?
A. The FDA has determined that they will allow Valsartan to be sold if their NDMA level is below that very minimal threshold.
Q. If the NDMA level is below that threshold, but the NDMA is not contained in the RLD, would the generic be adulterated?
MR. SLATER: Objection.
You could answer.
A. It is still adulterated.
Q. When you use the phrase "cohort of concern," what is that phrase from?
A. That's in the guidance document that where -- I don't -- the name is -- talks about assessing genotoxic and carcinogenic impurities.
Q. I'm sorry, what is that?
A. We can pull them up. Um -- I'd like to

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look at them, 7, ICH M7. I believe it's in M7, if we could pull that up.
Q. I just was asking what document it's in. We don't have time really to reread the document right now.
Are you offering an opinion that ZHP intentionally sold Valsartan with NDMA or NDEA impurities?
A. I'm not testifying that they did it intentionally.
Q. Do you know why ZHP did not find NDMA when it tested Valsartan using GCMS?
A. No, I don't know why.
MR. SLATER: Objection, lack of foundation.
Q. Are you offering an opinion that ZHP violated EMA guidelines?
A. I'm sorry, can you tell me what specific guideline you're speaking of?
Q. Are you familiar with EMEA guidelines?
A. Some.
Q. Are you offering an opinion that ZHP violated them?
A. Again, which guideline specifically are we talking about?

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Q. Are you offering an opinion that ZHP violated any EMEA guidelines?
A. Yes.
Q. Which ones?
A. There's an EMEA guideline of a -- excuse me -- that covers or discusses the limits of genotoxic impurities.
Q. Is that guideline still in force?
A. To my knowledge.
Q. Is there any other EMEA guideline that you believe ZHP violated?
A. Not off the top of my head.
Q. If we could go back to Exhibit 2.
MR. SLATER: What's Exhibit 2?
MS. MILLER: The supplemental reliance list.
MR. SLATER: Got it.
Q. It states here that you read the expert report of Ali Afnan.
A. Yes.
Q. Who is Ali Afnan?
A. He's an expert in the field of nitrosamines.
Q. Were you familiar with him before this litigation?

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A. No.
Q. Do you know what his background is?
A. No.
Q. Do you know what opinions he offered?
A. Only the opinions that were in his report.
Q. Do you recall any of them?
A. Again, we can go to my report and look at the various places that I've referenced his report.
Q. Did you reference Ali Afnan's report in your report?
A. Again, let's go see. I'd be more than happy to do a quick scan.
Q. Do you know without looking at your report whether you referenced Ali Afnan's report in your report?
A. I don't know without looking.
Q. Okay. Moving down, there are six ZHP documents mentioned here. Do you see that?
A. Yes.
Q. Did you look at these six ZHP documents before you wrote your report or after?
A. I believe some of them prior to writing my report.

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Q. Which ones? Sorry.
A. And again, it's difficult for me to know when -- it's just the Prinston number and investigation regarding -- I'd be able to more specifically look up what that document is.
Q. Do you recall when you received the six documents on the supplemental reliance list that are from ZHP?
A. I don't know for sure when I got each of these.
Q. Do you know why they weren't on your original list of materials consulted?
A. Again, I'm not sure what some of those are. So could we --
Q. Are you saying you don't know what these documents are that are listed on your supplemental --
A. I don't know them by the Prinston numbers.
Q. They have titles afterwards, right?
MR. SLATER: Objection, argumentative. She's asked to see them to be able to answer your questions. You obviously don't want to show them to her. You can continue with this.
Q. They have titled on them. I'm just trying to understand if you know why they were not

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included on your original reliance list.
A. No. I don't know.
Q. Do you know why the two scientific articles were not included on your original reliance list?
A. You're talking about the two articles under the heading, "Scientific Materials"?
Q. Correct.
MR. SLATER: Your question is limited to that? Okay.
You can answer.
A. I don't believe I read those materials prior to my report.
Q. How about the five documents under "Regulatory Documents." Do you know why those were not included in your original reliance list?
A. No, I don't.
Q. Did you review the complete testimony of Dr. Najafi from January 18 and 24?
A. Yes.
Q. Let's turn to the next page. Did you review Dr. Hecht's deposition and all of these exhibits?
A. Yes.
Q. Did any of these exhibits to Dr. Hecht's

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deposition affect your opinions in this case?
MR. SLATER: Objection.
You can answer.
A. No, my opinion was not affected.
Q. Over the course of drafting your report, did you ever go to Plaintiff's counsel and ask for additional documents?
A. I believe I did.
Q. What documents were those?
A. That was -- that's a voluminous number of documents. I cannot recall, you know, we're talking three or four or five months ago that I was writing this report. I don't remember which exact documents I requested.
Q. Did Plaintiffs' counsel provide you with the regulatory documents that you cite in your reliance list, or did you identify them on your own?
A. Can you go back up to the regulatory documents, please?
They supplied them to me.
Q. How about the ICH documents, did Plaintiffs' counsel supply those to you as well?
A. Yes.
Q. When did you first become aware that the TA with quenching process could lead to the formation

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of NDMA?
A. After I was retained in this case.
Q. How many hours did you spend preparing your report and reviewing documents?
A. Oh, my goodness. I would need to go back to my invoice. I would say somewhere around a the hundred-hour range, hundred-plus hours.
Q. How much time did you spend preparing for your deposition?
A. I don't have an exact number. I haven't added it up. But it's somewhere in the 30 to 40-hour range.
Q. Did you meet with Plaintiffs' counsel to prepare for your deposition?
A. Yes.
Q. Was that via Zoom?
A. Yes.
Q. How many times?
A. Again, I don't remember exact number.
Q. How many times this week did you meet with Plaintiffs' counsel, in the last week?
A. In the last week? I would say four to five times, I guess.
Q. Did you review any defense expert reports in preparing for your deposition?

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MR. SLATER: Objection, asked and answered.
Q. Have you provided an answer?
THE WITNESS: Would you repeat the question, please?
MS. MILLER: David, go ahead.
(Record read.)
A. Yes.
Q. Which ones?
A. David Chesney.
Q. When did you review that?
A. Prior to writing my report.
Q. My question was preparing for your deposition?
A. Oh, in preparation for my deposition?
Q. Yes.
A. Can you please repeat the question then?
Q. Did you review any defense expert reports in the process of preparing for your deposition?
A. Not that I can recall at the moment.
Q. Have you heard of a company called MSP?
A. MSP? No.
Q. You said that during the break you'd be able to come up with a more complete list of your

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InCompliance Solutions clients. Did you do that?
A. No, I haven't had a chance to do that.
MS. MILLER: Can we take a break now for you to do that?
MR. SLATER: What's the question that you want to take a break for? I missed it. Is it something about her clients, you want --
MS. MILLER: A list of her InCompliance clients.
MR. SLATER: First of all, to the extent her clients may be confidential, she's not going to produce that, obviously.
MS. MILLER: You've already said that.
MR. SLATER: Well, if you want her to do that, we're not going to do it off the record. So if you want her to hunt and do research for you, it's going to be on your time.
MS. MILLER: No, we're going to go off the record.
MR. SLATER: I'm not agreeing to that. I'm telling you right now if you want her to go do a hunt for the names of her clients, just like with any other witness. You've asked her. She's told you what she recalls.
The idea that you would let me make one

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of your experts go and search for documents or information on their time and hold the deposition, there's no way in the world I would ask that. There is no way you would allow it. I'm not agreeing, so please, you can hold that one for Judge Vanaskie, because I'm not going to agree to stop the clock and send Dr. Bain on a treasure hunt.
MS. MILLER: Are you finished, Adam?
Q. Do you recall the name of your Canadian client?
A. I do not remember the name of the Canadian client.
Q. Do you recall the name of your Italian client?
A. I don't. I do not and, can I please clarify, the audit that I did of the Canadian company who manages clinical trials did not retain me. I was retained by the company that uses their services.
Q. Okay. Through Pharmatech?
A. No.
Q. Was the Canadian manager Pharmatech?
A. Pharmatech had nothing to do with this audit.
Q. Did Pharmatech have anything to do with the Italy audit?

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A. Yes.
Q. How about AccuLab?
A. Yes.
Q. Can you recall any of your other Pharmatech clients?
A. In what time frame?
Q. Any time frame.
MR. SLATER: Only if your contracts or relationships with them are not confidential. You should not violate a confidentiality agreement to answer this question.
MS. MILLER: Adam, you've repeated that multiple times.
MR. SLATER: I'm sorry, did it bother you that I said it to remind her of that? I'm trying to keep her from violating a confidentiality provision. I'm sorry, if that -- if that -- you felt like that was inappropriate. I thought it was smart to tell her because it's her first deposition.
A. The other thing is, Adam's right. The firm that retained me to do their audit in Canada, I would not want to discuss their name.
Q. Are there any other clients you've had, whether through Pharmatech or generally, through InCompliance, whose names you recall and can

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identify?
A. I had a client that was -- the client was called L-3. And they are, again, a company that hires consultants to do work for them.
Q. What do you mean by that?
A. The company comes to L-3 and says, "Hey, can you please hire a consultant to come out and do an audit for us."
Q. And when was that?
A. That was around the time frame mid-late '20-'21 to mid-early -- you know, early-mid '20-22.
Q. And were any of those companies API manufacturers --
A. No.
Q. -- that set you up with -- and do you recall the names of any of those companies?
A. Symmetric. It was medical devices, it was not drug-related.
Q. What percentage of the work you do for InCompliance involves medical devices?
A. That depends on the time frame you're talking about.
Q. Over time.
A. Again, I -- hard to quantify. Because some of the jobs are quite short, right? Only two

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weeks. Some stretch for six to eight months. So difficult for me to say. And, you know, and they may overlap with something else.
Q. How about if we asked the question a little differently to make it easier for you to respond. What percentage of your clients that you've had for InCompliance Solutions, including clients that you got through Pharmatech and L-3, would you say are medical device companies?
A. Fifty percent.
Q. And what were the other fifty percent? How would you break that down?
A. Again, because one client can last a very long time, right? So if you're talking eight clients, or are you talking number of hours?
Q. I clarified my question. I said the types of clients you have. And you said about fifty percent of your clients are medical device manufacturers. How would you classify the other fifty percent of your clients?
A. Addressing it as you said now, I'm sorry if I misspoke previously, about 70 percent of my clients have been medical device and probably around 30 percent have been drugs or biologics.
Q. And those clients are drug or biologic

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manufacturers?
A. Yes.
Q. And none of them are API manufacturers?
A. No.
Q. And do you know what percentage of your clients have received warning letters from FDA?
A. I have no idea.
Q. Okay.
MS. MILLER: I'm going to reserve the rest of my time for, to go after Adam -- wait, before -- before you go, Adam, I think we should check to see if Teva or Torrent have any questions.
MR. RUBENSTEIN: This is Brian Rubenstein from Greenberg Traurig representing the Teva defendants. I have just a few questions for Dr. Bain.
EXAMINATION BY
MR. RUBENSTEIN:
Q. Good evening, Dr. Bain. My name is Brian Rubenstein and I'm with the law firm Greenberg Traurig, and I represent the Teva defendants. I will do my best to keep this brief. I think I only have a few questions for you.
Are you familiar with the Teva defendants and their role in this case?

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A. Familiar with them in what context?
Q. In the context of this case.
A. I know that Teva is involved in this case.
Q. Is it your understanding that Teva is involved in this case as a finished dose manufacturer of Valsartan?
A. Yes.
Q. Earlier, I believe you testified that you worked for Watson from 2003 to 2005, is that right?
A. Yes.
Q. And are you aware that Watson is now a part of Teva?
A. Yes.
Q. And you testified that while you were with Watson, it was under a consent decree and a warning letter for CGMP violations during the time you worked there; is that right?
A. Yes.
Q. And to your knowledge, were any of those CGMP violations that were the subject of the warning letter or the consent decree related to Valsartan?
A. I do not know.
Q. To your knowledge, were any of the GMP

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violations that were subject of the warning letter and the subsequent decree related to its manufacturing facility located in Malta?
A. You're asking about the consent decree and the warning letter? I don't know. I didn't look into the consent decree or warning letter.
Q. Okay. And I know that Ms. Miller asked you this earlier, but I just want to be clear. You don't offer any opinions or criticisms of Defendants Teva or Torrent in your report, do you?
A. No, I don't.
Q. And if called to testify at trial in this matter, you don't intend to offer any criticisms or opinions of Defendants Teva or Torrent, right?
MR. SLATER: Objection. She'll answer whatever questions are asked of her.
You can answer the question.
A. That would depend on the question.
Q. But as you sit here today, there are no criticisms of Teva or Torrent in your report that you submitted.
A. I did not have any criticisms of Teva or torrent in my report, that's correct.
Q. Have you seen any documents from the FDA or any other regulatory agency deeming any of Teva's

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finished dose Valsartan products adulterated?
A. I don't remember specifically seeing Teva's parts or lots being adulterated. I don't remember seeing.
Q. Okay.
MR. RUBENSTEIN: That's all the question I have.
THE WITNESS: I need to turn a light on in my room here, it's getting dark.
(A pause in the proceedings.)
MS. MILLER: Adam?
MR. SLATER: Does anyone else have questions? Torrent?
A VOICE: Nothing from Torrent, thank you.
MR. SLATER: All right, we'll take ten and come back.
VIDEOGRAPHER: The time is 3:10 p.m. We're off the record.
(Recess taken.)
VIDEOGRAPHER: The time is 3:32. We're back on the record.
(Continued on following page.)

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EXAMINATION BY
MR. SLATER:
Q. Dr. Bain, I'm just going to go over a couple of things with you. And let me just figure out my first question.
Do you have your report handy?
A. Yes, I do.
Q. Would you go to page 37, please. The very bottom.
A. Okay.
Q. This is a part of the report where you talk about Dr. -- let me start over. Looking at page 37 of your report, this is the part where you're talking about testimony Peng Dong gave on behalf of the company, correct?
A. Yes.
Q. Actually, the first thing that I want to do is actually go to the top of page 37. And do you see where you summarize some testimony from Peng Dong, and he confirmed that, in the context of the DMF amendment to the zinc chloride process which refers to applicable "laws and regulations" that included the January 1, 2007 EMEA CHMP, which is the European regulators' guideline applicable to genotoxic impurities, and required "the risk

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assessment on genotoxic impurities"?
A. Yes.
Q. And you were asked some questions about whether guidances and ICH, etc., were legally binding and, in this context, when the company actually applied those guidances and ICH guidelines, etc., at that point, are they obligated as a matter of CGMP to actually comply with them and fulfill the obligations in those guidelines?
A. Yes, they are.
Q. And the failure to do so would be a GMP violation, correct?
A. Yes, it would.
Q. And you can see in that same paragraph, the last four lines, you agreed that the EMA guideline also provided that "as low as reasonably practical guidelines" would not apply to a structure of very high concern, for example, N-Nitroso compounds, and he could not say that the person responsible for the risk assessment actually "paid attention" to this provision, in terms of not having thresholds for N-nitroso compounds. You were aware of that testimony, too, right?
A. Yes, I was.
Q. And then you look a little further down

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in the third paragraph on that page, you see where Mr. Dong's testimony is summarized and he agreed that the risk assessments performed by ZHP were also governed by the FDA draft guideline, "Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches." So he had confirmed that in his testimony as well?
A. Yes.
Q. And you can see at the end of that paragraph, that he did confirm that ZHP was required to reference scientific literature in performing the risk assessment, do you see that?
A. Yes, I do.
Q. And if you hold that page and go back to page 5, if -- not page 5, let me find it -- page 9, you actually reproduced the stipulation that ZHP entered into in this litigation on page 9 and 10 and 11, correct?
A. Correct.
Q. If we go to page 10, 3(a), it says in 3, "ZHP states it was required to perform a risk assessment in connection with the process change to the zinc chloride process. ZHP further states the following." And then in 3(a), "ZHP states that the scientific research relied on to use DMF as part of

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the zinc chloride process did not include scientific research into the potential decomposition products of DMF under the conditions of the zinc chloride process."

Do you see that?

A. Yes, I do.

Q. And when you put that together with Mr. Dong's confirmation that ZHP was required to reference scientific literature in performing the risk assessment, is it your opinion that ZHP violated CGMP by failing to actually do the scientific research into the potential decomposition products of DMF under the conditions of the zinc chloride process?

A. Yes.

Q. Let's go back to page 37. And at the very bottom, it states in your report that "Mr. Dong testified with regard to the varied NDMA levels seen in the Valsartan API produced in the east and west zones and Chuannan," that's C-h-u-a-n-n-a-n, "and addressed the discussion in the TEA deviation investigation report as to the factors impacting the NDMA levels," and it goes on, do you see that?

A. Yes, I do.

Q. If you go to the next page at the top of

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the page, I just want to read a little more of that paragraph. In the second line it says, "Further, ZHP confirmed that there was a 'lack of default description in the production processes.' Due to the inaccurate description of some of the parameters in the process, there might be likelihood of fluctuation between different workshops or different batches manufactured in the same workshop, which eventually led to the difference in amount of residual impurities...the residual amounts of NDMA in Valsartan API batches."

Do you see that?

A. Yes, I do.

Q. So first of all, as you stated, you found that this is in violation of GMP because there was a failure to have consistent repeatable manufacturing, correct? That's your opinion?

A. That's correct.

Q. And also the fact that they were not actually having consistent production conditions, that raises questions as to the temperature applied. Counsel asked you a lot of questions about temperature but ZHP confirmed they didn't consistently manage the production conditions which would likely include the temperature and the time for

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which the process, different stages of the process are carried forth, etc. Right?

A. That's right.

Q. And in that context, you were asked about Exhibit 4, which you don't have to pull up. It was the World Health Organization document from 2001 entitled, N,N-Dimethylformamide. Remember you were asked some questions about that?

A. Yes, I remember.

Q. And counsel asked you about parts. I'm going to ask you about page 15, under section 2. I'm just going to read this to you in the interests of time.

A. Okay.

Q. It says, on page 5, at the bottom right, under section 2, titled, "Identity and Physical/Chemical Properties," the second half of the first full paragraph, "DMF sold commercially contains trace amounts of methanol, water, formic acid and dimethylamine," do you see that?

A. Yes, I remember seeing that.

Q. And you saw that Dr. Hecht talked about that in his deposition as well, correct?

A. Yes, I saw that.

Q. And did you see any indication that ZHP

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ever documented, either at the time or in their deviation investigation reports, that they evaluated the DMF they were buying to see if it came in with dimethylamine already as an impurity of the DMF?

A. I did not see any evidence of that.

Q. So in your opinion, based on this information, and all the information available to you, should ZHP have been aware that the DMF could come through the door with dimethylamine on it, and wouldn't even need to be formed through degradation?

A. That's correct.

Q. You were asked a few questions about whether you were qualified to provide certain opinions. Are you an expert on the legal standard for being qualified to testify as an expert in this case?

A. No.

Q. Okay in terms of what you did here and what you documented in detail in your report, was the evaluation and the methodology you applied in performing that evaluation fully consistent with the approaches that you take in your professional work outside of this expert assignment, and fully within your knowledge and expertise with regard to subjects of quality, quality assurance, risk assessment, the

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points that you talk about in your report and you've offered the opinions on?
A. Yes, they are the same.
Q. Can we go to page 5 of your report, please. Looking at the paragraph in the middle of the page, a little more than halfway down that paragraph, you write, "Guidance documents do not establish legally enforceable rights or responsibilities. However, in practice, the guidance is adopted by manufacturers and considered to be binding. 21 CFR section 10.115(d)(2) states, "You may choose to use an approach other than the one set forth in the guidance document. However, your alternative approach must comply with the relevant statutes and regulations. FDA is willing to discuss as alternative approach with you to ensure that it complies with the relevant statutes and regulations."
Do you see that?
A. Yes, I do.
Q. So when you were asked during the deposition the specific regulation that says what you had testified to, that those guidelines may not be legally enforceable at the outset, but once they are applied, they become legally enforceable, is that the section you were talking about in the CFR?

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A. Yes, that is.
Q. Okay. And in terms of this, in this context, just to give a few examples -- bear with me for one second -- let's go to page 37. That might not be the page I wanted to go to. Bear with me one second.
(A pause in the proceedings.)
Q. Ah, page 25, I apologize. On page 25 of this, of your report, you're talking about the modules that are part of the DMF amendment that was dated November 10, 2013, do you see that's the first full paragraph?
A. Yes, I do.
Q. And this is the module that is titled, "Impurities," where the DMF actually provides information about the evaluation of impurities with this zinc chloride process, correct?
A. Yes, that's correct.
Q. And you state in your report that this module indicates on page 147 of 172 that the application of the FDA draft guideline, "Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches," is applicable to the applications for existing active substances. And the module unequivocally states, on pages 148 to 149,

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that, "All the potential impurities were evaluated. No high-potency genotoxic N-Nitroso compounds are among the impurities and the impurities pose no genotoxic risk in Valsartan."
Do you see that?
A. Yes, I do.
Q. First of all, this is confirming that once again, in the DMF, that ZHP actually confirmed that they applied and were obligated to conform to that FDA draft guidance, correct?
MS. MILLER: I'm going to object on the ground that I thought Dr. Bain was the expert, not Adam, and Adam has just provided about 15 minutes of testimony.
MR. SLATER: Thank you.
Q. Looking at this as well, where it says that all potential impurities were evaluated and no high potency genotoxic N-Nitroso compounds are among the impurities, and the impurities pose no genotoxic risk in Valsartan, was that an accurate statement by ZHP in its DMF that there were no N-Nitroso compounds?
A. It is not a true statement.
Q. And in your opinion, is that the result of the inadequate risk assessment that was performed

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up front and then on a continuing basis?
A. Yes.
Q. And then I'm not going to read the whole thing but the next paragraph, does it have the same language with respect to the TEA with sodium nitrite quenching, DFM amendment 5, January 20, 2012?
A. Yes, it does.
Q. And are the opinions the same with regard to the statements in that DMF module?
A. Yes, they are.
Q. Let's go to page 30 of your report, please. In the middle of the page where you're talking about some testimony from Eric Gu, the third paragraph says, "Mr. Gu was also asked about ICH Q3(a) which was in effect as of 2006, and confirmed that the ICH guidelines provided 'very important principles that guided the development process.' He confirmed that section 3.1 required ZHP to summarize the actual and potential impurities. This summary should be based on sound scientific appraisal of the chemical reactions involved in the synthesis," etc., "impurities associated with raw materials that can contribute to the impurity profile of the new drug substance and possible degradation products."
And he agreed that dimethylamine was a

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possible degradation product of DMF as used in the zinc chloride process, do you see that?
A. Yes.
Q. So first of all, did Mr. Gu, speaking for the company, confirm that ICH Q3 applied to the zinc chloride process?
A. Yes, he -- he did agree.
Q. And that would -- would that also apply to the TEA with sodium nitrite process as well?
A. Yes, it would.
Q. And again, I'm picking out some examples, did you take all this into account in forming your opinions?
A. Yes, I absolutely did.
Q. And were you asked by counsel to list every single ICH or guidance or any other source of authority that you're relying on? Do you have those listed in the report?
A. They are throughout the report.
Q. When you were asked about whether the risk assessment was adequate or not, and talked about whether or not -- let me rephrase. Let go to page 51.
Let me know when you're there.
A. I'm there.

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Q. At the bottom of page 51, the last paragraph, you state, "In this connection, Mr. Du was shown a draft of the deviation investigation report which stated, 'Due to insufficient extent and depth of process research at the early stage, as well as insufficient study and understanding of potential genotoxic impurities, only side reaction products and degradation products were studied,' and was unaware of the further reaction between degradation products and raw material," do you see that?
A. Yes, I do.
Q. So this language didn't make it into the final report, right?
A. That's right.
Q. But do you agree that ZHP conducted an insufficient extent and depth of process research --
A. I agree --
Q. -- stage, as well as insufficient study and understanding of potential genotoxic impurities?
A. I do agree.
MS. MILLER: Objection, again, Adam, to your ongoing testimony.
MR. SLATER: Thank you.
Q. You were asked about whether or not the NDMA or NDEA in the Valsartan was above or below a

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threshold percentage. I think counsel quoted .1 percent, remember these questions?
A. Yes.
Q. When you offered your opinions in this case, and is it actually discussed in your report, that NDMA and NDEA are cohort of concern substances that would not be subject to a threshold?
A. Yes, I discussed it in my report.
Q. You were asked about whether or not ZHP intentionally sold their Valsartan with NDMA and NDEA towards the end of defense counsel's questioning, do you remember that?
A. Yes.
Q. Are you familiar with the July 27, 2017 e-mail that was testified about by Min Li when he testified on behalf of the company?
A. Yes. I'm aware of that.
Q. And according to Min Li's testimony, where he was reading the e-mail and agreed that it said that there was NDMA in Valsartan and it was caused by the sodium nitrite quenching, you see that?
A. Yes, see that.
Q. At that point, once it was known to ZHP, could there be any justification whatsoever for them to consider to -- to continue to sell that Valsartan

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knowing there was NDMA in it and knowing how it was being created through the sodium nitrite quenching?
MS. MILLER: Objection, mischaracterizes the document, mischaracterizes testimony. Also, Adam is continuing to testify.
Q. You can answer. Was there any justification for ZHP to sell that Valsartan once they knew that there was NDMA in the Valsartan and it was caused by the sodium nitrite quenching?
MS. MILLER: Objection.
Q. You can answer.
A. There was no justification for them to sell Valsartan once they became aware of the impurity.
Q. And when Dr. Lin, who wrote the e-mail of July 27, 2017, said that if a similar substance was found in Irbesartan, that would be a serious CGMP problem, you agree with that, right?
A. I do agree with that.
MR. SLATER: One second, stay on the record.
(A pause in the proceedings.)
MR. SLATER: I have no other questions.
MS. MILLER: I need ten minutes. Off the record.

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VIDEOGRAPHER: Time is 3:55. We're going off the record.
(Recess taken.)
VIDEOGRAPHER: The time is 4:20, we are back on the record.
FURTHER EXAMINATION
BY MS. MILLER:
Q. Mr. Slater spoke briefly about temperature. Are you aware of any evidence that DMF ever reached the boiling point during the manufacturing process for Valsartan?
A. I'd have to go back and research that. I don't know off the top of my head.
Q. Are you aware of any evidence that ZHP did not know the temperature of DMF during the manufacturing process?
A. I only know that there was testimony saying that their processes were not in control.
Q. Are you aware of any evidence that the manufacturing took place at a temperature different or higher than [redacted] degrees?
A. I haven't seen anything.
Q. Are you aware of any evidence that the DMF used in the manufacturing process by ZHP contained dimethylamine when it was received from

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suppliers?
A. I'm not aware. I don't know that it was tested for.
Q. Did you ask Plaintiffs' counsel to document to determine what ZHP did to confirm the purity of the ingredients it received from suppliers?
MR. SLATER: Objection, lack of foundation.
You can answer.
A. I did not ask for any documentation.
Q. Did you ask Plaintiffs' counsel for any certificates ZHP received from its DMF suppliers?
A. No, I did not.
Q. Have you ever worked with DMF as a solvent?
A. Not that I can recall.
Q. Do you know whether a reasonable chemist would test DMF provided by a supplier for dimethylamine?
A. I have no idea what a reasonable chemist would do.
Q. Adam read some portions of your report to you, many portions of your report, but I'm just going to focus on one that uses the term, "High potency genotoxic." Do you recall that?

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A. Can you tell me what page --
Q. I don't recall the page it was, but I just wanted to know if you could tell me what the term "high potency genotoxic" means.
MR. SLATER: Objection. That's actually lack of foundation. The phrase was -- that's not complete. You're not actually reading the complete phrase.
Q. Do you know what the phrase "high potency genotoxic" means?
MR. SLATER: Objection. Same reason.
Q. Is there a definition that you're aware --
MR. SLATER: I'm sorry, are you withdrawing the prior question now and --
MS. MILLER: Back to the same question, Adam --
MR. SLATER: So why while she's looking for -- I'm sorry, while she's trying to work to answer the question, badgering her with follow-up questions is very confusing.
MS. MILLER: When you say she's working to answer the question, we had an agreement at the beginning of this deposition that, if the witness was going to look at any documents, she would tell me in

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advance.
Q. So if you're currently looking at documents, I need to know which ones they are.
MR. SLATER: How would I know if she's looking at documents?
Q. -- when I asked you before if you were looking at documents, you said no. Are you currently looking at a document?
A. The only document I have up is my report.
Q. Okay. And are you currently looking at your report?
A. My report is up but it's overlaid with the gallery picture we have here.
Q. Got it. It looked like you were reading something.
A. No.
Q. And seemed to suggest that you were reading something. And so my question to you was, just to go back to it, are you aware of any definitions of the term "high potency genotoxic?
MR. SLATER: Objection, again. It's a partial phrase. I'm not sure why you're not able to ask the question with the actual phrase that I read. I'm not understanding why you're asking half a phrase

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but I guess you can do it if you want.
A. I am not aware of a specific location for the definition of "high potency genotoxic."
Q. Have you ever used those words before?
A. During what time frame?
Q. Ever.
MR. SLATER: Doctor, you're allowed to use your report. Just because counsel is trying to intimidate you into not doing it, I'm instructing you, you're allowed to do it. Please.
Q. He's not the witness here, but I'd appreciate if you would answer my question.
MR. SLATER: What I'd appreciate is if you didn't try to intimidate Dr. Bain from looking at her report to find the words you're asking for, so she can actually answer the questions in a reasonable way.
MS. MILLER: I'm so intimidating, Adam.
MR. SLATER: When you ask questions with partial phrases that are deliberately confusing, it's not practically --
MS. MILLER: Okay. I thought you said you wanted to finish up quickly.
Q. Are you familiar --
MR. SLATER: I didn't say that.

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Q. -- with the term "high potency genotoxic"?
MR. SLATER: Objection, again.
A. Am I familiar with that phrase? Yes.
Q. And what does it mean to you?
A. A substance that could cause cancers.
Q. Is there a difference between a substance that's genotoxic and a substance that's high potency genotoxic?
A. I'm not -- I don't know the differentiation between the two. I mean...
Q. Adam mentioned a 2017 e-mail in his questioning, do you recall that?
A. Yes.
Q. And you're familiar with that e-mail?
A. Yes.
Q. Are you aware that e-mail is written in Chinese?
A. Yes.
Q. Did you do anything -- did you read it in Chinese or in English?
A. English.
Q. And what was the e-mail about?
A. Can we pull the e-mail up, please?
Q. Well, Adam asked you questions about it

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without you having to pull it up and I'd just like to --
MR. SLATER: Argumentative. Memory test. Completely inappropriate question.
I'm going to instruct you, Dr. Bain, if you want to find it in your report where it's discussed, you're allowed to do that to answer the question even though counsel keeps interrupting you. You're allowed to do that.
Q. I haven't interrupted you a single time today. I'm asking you if you recall sitting here today what the gist of the entire e-mail was about.
A. The e-mail discussed the nitrosamine formation, the potential -- again, I -- I would like to pull up the e-mail so I get the verbiage correct. And we could reference it in my report as well if you can tell me the section where you're --
MR. SLATER: Doctor, are you able to search your report on your computer for words?
MS. MILLER: Adam, you're interrupting the witness and --
MR. SLATER: I'm sorry, I'm talking.
MS. MILLER: -- yes, you interrupted the witness in the middle of a sentence. It's highly inappropriate and you know that.

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MR. SLATER: She's asking --
MS. MILLER: Please wait until she's done answering and then you can talk.
Q. You were in the middle of answering my question. I'd like to you continue your answer. What were you saying?
A. I'd like to look at the e-mail or have you point to me in my report where you're discussing this.
Q. Do you recall whether the e-mail references Irbesartan?
A. Yes, it does.
Q. Do you know what Irbesartan is?
A. It's another drug.
Q. Is Irbesartan the same molecule as Valsartan or a different molecule?
A. I don't know that answer.
Q. Do you know -- do you recall whether the e-mail references deacylated Valsartan?
A. I don't recall.
Q. Do you know what deacylated Valsartan is?
A. No, I don't.
Q. Do you recall whether there was a patent attached to the e-mail?

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A. Patent attached?
Q. Um-hum.
A. I did not see a patent.
Q. Did the e-mail reference an attached patent?
A. Again, if I could see the e-mail --
Q. Do you recall?
MR. SLATER: Before you ask the next question, hold on, don't ask another question. I'm going to say something --
Q. -- whether the e-mail --
MR. SLATER: -- I'm sorry, Ms. Miller, I'm trying to talk, and -- say something to the witness before you ask another question.
Dr. Bain --
MS. MILLER: You're -- what you call instructing the witness is referred to generally as coaching the witness.
MR. SLATER: It's really not, because she keeps asking to see the document and you keep telling her, asking questions and blowing over -- Dr. Bain, if you want to see the document, find it yourself, pull up your report, search within it and find what you want and stop acting like she's in charge of telling you what you're allowed to do.

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Please.
Q. Do you recall whether there was a patent attached to the e-mail?
A. I don't remember.
Q. Okay. And do you recall whether there was any reference to Impurity K in either the e-mail or any attachment?
A. I don't remember. But I am going to -- you asked me to tell you when I'm going to pull something else up, and I'm going to pull up that e-mail.
Q. Have you ever heard of Impurity K?
MR. SLATER: I'm sorry, she said she's going to pull up the e-mail so could you wait until she's --
MS. MILLER: My question doesn't relate to that. My question --
MR. SLATER: She's busy pulling up the document, so I don't want her to have to answer a question while she's looking for a document.
MS. MILLER: There's no pending question about the e-mail itself.
Q. I'm asking if you've ever heard of a substance called Impurity K.
MR. SLATER: Counsel, that's a

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completely misleading statement you just made. You know what you're doing. She's allowed to look for the document to answer further questions along this line and you can't stop her like you're doing and talking over her.
MS. MILLER: I'm not talking over -- actually, Adam, the only person in the last ten hours who has talked over anybody is you.
Q. Do you know what Impurity K is?
MR. SLATER: Doctor, first of all, object to how you're proceeding. If you need to look at the document, you're allowed to. And you don't have to wait for permission and you don't have to answer the question until you find what you want to reference. You're allowed to do that.
I'm not coaching the witness, I'm letting her know what her rights are as a witness in a deposition. Every time she asks to see a document, you bulldoze over her and you don't let her do it.
THE WITNESS: I asked to be guided in my report to the section you were speaking about.
Q. I'm not speaking about any section of your report so there's nothing I can point you to. I'm just asking if you know what Impurity K is.
A. I do not know what Impurity K is.

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Q. Did you conduct any investigation of the circumstances that led to this e-mail?
A. No, I did not.
Q. Did you do any research about the chemical formulations that were included in the e-mail?
A. No, I did not.
Q. Did you take any steps to evaluate the chemical formulas that are that are set forth in the e-mail?
A. No, I did not.
Q. Do you know whether the chemical formulas set forth in the e-mail bear any relationship to how NDMA was formed in Valsartan?
A. No, I do not.
Q. Did you ask to speak to anybody at ZHP to understand the circumstances that led to the e-mail?
A. No, I did not.
Q. Did you take any steps to determine whether the translation you read of the e-mail was accurate?
A. No, I did not.
Q. Did you take any steps that we didn't discuss thus far to understand the e-mail?

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MR. SLATER: Objection.
You could answer.
A. Did I take -- the question was did I take any other steps to understand the e-mail?
Q. Understand the context of the e-mail.
A. I discussed it with counsel.
Q. Did you ever ask counsel for the patent that was attached to the e-mail?
A. No, I did not.
Q. Do you recall whether Jucai Ge testified in 2022 about the meaning of the e-mail?
A. Can you spell the name, please?
Q. J-u-c-a-i, G-e.
A. Want to give me a chance to look through my report?
(A pause in the proceedings.)
A. I'm sorry, you said the spelling was J-u-c-a-i, correct?
Q. Um-hum, G-e.
A. What specifically did you --
Q. Do you recall whether she testified in 2022 about the interpretation of the e-mail?
A. I'd have to read this testimony that she gave in its entirety, if you'll give me time to do that.

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Q. I'm just asking if you recall whether or not she testified about interpretation of that e-mail in her 2022 deposition.
A. I don't recall without, again, going through my report.
Q. Does your report quote or reference Jucai Ge's 2022 deposition in which she describes what her understanding of the e-mail is?
A. Again, I'd have to go through my whole report and look to see if I have a reference to that.
Q. Would you have to go through your whole report, or would you just have to go through the portion of your that refers to Jucai Ge's deposition?
A. I'd have to go through my whole report to ensure that I hadn't discussed it in some other area other than under her testimony.
Q. So short of reading all 76 pages of your report, you can't tell me right now whether Jucai Ge testified in 2022 about her understanding of this e-mail?
A. I don't remember, no.
Q. Okay.
MS. MILLER: I'm going to reserve the rest of my time in the event Adam has further questions.

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Justin, how much time do we have?
VIDEOGRAPHER: Just off the record to add it all up --
MS. MILLER: Let's go off the record.
VIDEOGRAPHER: Time is 4:37, we're off the record.
(Discussion off the record.)
MR. SLATER: I have no other questions. We're done.
MS. MILLER: I have one final question.
MR. SLATER: I thought you had just closed your record. We're done.
MS. MILLER: I have one final question.
VIDEOGRAPHER: The time is 4:38, we're back on the record.
BY MS. MILLER:
Q. How many computer screens do you have before you today?
A. Two.
Q. What's on the other screen?
A. I have, one screen has up my report, the other screen has up my list of folders.
Q. And were there times today when you turned to that other screen and read materials from it without telling me?

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A. No. I only have the list of folders. There was nothing to read.
Q. The other screen that you have, next to that screen, the one that you're looking at right now?
A. Has my report.
Q. Did you look at that screen at all today?
A. Did I ever look at it? I looked at the screen today, of course.
Q. Could you identify for me the times when you looked at your other computer screen?
A. I'm going to tell you I've moved my report back and forth, because there's times you're -- because I have a gallery view, sometimes you are in one place, sometimes you're in another place. And so I have to move the display so that I could see you.
Q. At the beginning of your deposition, did you tell me that you had two monitors in front of you today?
A. I wasn't asked.
Q. When I asked you at the beginning of the deposition what was in front of you, you said there was just one screen with the deposition on it.

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MR. SLATER: Objection, lack of foundation. Mischaracterization. Come on. Is this really what we're doing now? Go ahead, you do it, Jessica. Go ahead.

A. I do not remember testifying that there was only one screen in front of me, ever.

Q. On your second screen that I didn't know about until two minutes ago --

MR. SLATER: Objection.

Q. -- can you --

MR. SLATER: Really out of line.

Q. -- can you let me know everything that was on that second screen today?

A. Yes.

MR. SLATER: One second. Objection, lack of foundation, mischaracterization.

You can answer, Dr. Bain.

A. I will say there was one other thing that was up earlier and that was the company who pulls up documents for us. I've had that screen up during the time that we were using the -- their services -- their services.

Q. There was a point in the deposition when you looked toward your second screen and I asked if you were reading a document and you said you weren't.

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What were you doing at that point when you were looking over at your second screen?

MR. SLATER: Objection. Come on. Argumentative, harassing.

You can answer, Dr. Bain. You can answer the accusation from counsel.

A. I was not looking at any documents. I had no other documents open. I had my report and I had two screens as I said. One has the report. The other has my list of files and for most of the time, it also had up the company's documents system, when you were going to display documents. I don't remember what their name is, Novak or something.

(Continued on following page.)

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Q. So is it your testimony that, when you were looking at your second screen earlier today, and I asked if you were reading anything, that you were not actually reading anything?

A. I was not actually reading anything.

MS. MILLER: I'm finished. Have a good evening.

MR. SLATER: You have a good evening, too, Jessica. Have a nice night. 'Bye, everybody. We're out.

VIDEOGRAPHER: The time is 4:41. We're off the record.

(Time noted: 4:42 p.m.)

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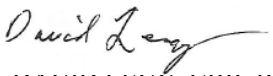
C E R T I F I C A T E.

I, DAVID LEVY, a certified court reporter and notary public of the State of New Jersey, certify that the foregoing is a true and accurate transcript of the stenographic notes of the deposition of said witness who was first duly sworn by me, on the date and place as hereinbefore set forth.

I FURTHER CERTIFY that I am neither attorney, nor counsel for, nor related to or employed by, any of the parties to the action in which this deposition was taken, and further that I am not a relative or employee of any attorney or counsel in this place, nor am I financially interested in this case.

IN WITNESS WHEREOF, I have hereunto set my hand this 2nd day of February 2023.



DAVID LEVY, CRR, RPR, CLR
LICENSE NO. 30X100234000

JURAT/ERRATA

I have read my testimony in the foregoing transcript and believe it to be true and correct with the following changes:

PAGE	LINE	FROM	TO

_____ _____
WITNESS SIGNATURE DATE

Subscribed and sworn to before me this ____ day of _____, 20____

Notary Public of the State of_____.

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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